IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

IN RE: HOFFBECK, LOREN JOHN	)
	)**APPEAL NO.** ______________
SERIAL NO: 10/753,119	)
	)
FOR: INBRED MAIZE LINE PH4GP	)**BRIEF ON APPEAL**
	)
FILED: January 6, 2004	)
	)
	)
GROUP ART UNIT: 1638	)

To Commissioner for Patents
Mail Stop Appeal Brief – Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sirs and Madams:

Please enter the following Brief on Appeal into the record.

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I. REAL PARTY IN INTEREST

The real party of interest in the present appeal is Pioneer Hi-Bred International, Inc. Pioneer Hi-Bred International, Inc. is a wholly owned subsidiary of DuPont.

II. RELATED APPEALS AND INTERFERENCES

An Appeal has been filed in U.S. Patent Application No. 10/742,319 and U.S. Patent Application No. 10/767,566 on behalf of Pioneer Hi-Bred International, Inc.

Many of the issues present in this case have already been before The Board of Patent Appeals & Interferences in the cases of *Ex parte William D. Griffith*, Appeal No. 2004-1968; *Ex parte Frances L. Garing*, Appeal No. 2004-2343; and *Ex parte Thomas B. Carlson*, Appeal No. 2004-2317. Therein, the Board determined that claims substantially similar to the claims at issue in the present appeal met the requirements of 35 U.S.C. § 112 and were allowable. These cases are accordingly relevant to the Board's decision in this appeal.

III. STATUS OF CLAIMS

Claims 1-10 were originally submitted January 6, 2004. In an Amendment dated May 19, 2005, Appellant amended claim 2. In a Supplemental Amendment dated August 4, 2005, Appellant added claims 11-30. In an Amendment After Final dated December 19, 2005, Appellant amended claims 7, 9, 22 and canceled claim 30. An Advisory Action was issued on January 12, 2006 entering Appellant's amendments. This is an appeal of the Final Rejection dated October 14, 2005, finally rejecting claims 1-10, 13-16 and 19-30. The claims here appealed are claims 1-10, 13-16 and 19-29.

IV. STATUS OF AMENDMENTS

An Amendment was filed on May 19, 2005. A Supplemental Amendment was filed on August 4, 2005. An Amendment After Final was filed on December 19, 2005.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The present invention relates to maize seed, plants and plant parts which are produced by crossing inbred maize line PH4GP with another, different maize plant. (*See* Specification, Tables 3A-3B, Specification pp. 41-42, and Table 4, Specification pp. 43-44). The invention also relates to a maize plant having all the morphological and physiological traits of PH4GP, wherein seed of PH4GP was deposited with the ATCC. (*See* Specification, p. 45, ll. 2-28). The invention further relates to a method of producing a maize plant in a maize plant breeding program which is the result of using the PH4GP line as a source of breeding material. (*See* Specification, p. 3, ll. 21-34). The invention further relates to a single locus conversion of PH4GP produced through backcrossing. (*See* Specification, p. 21, ll. 16-31; p 28, l. 23 - p. 33, l. 6). Material relevant to the appealed claims is described throughout the Specification.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Claims 19-24 stand rejected under 35 U.S.C. § 112, Second Paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

B. Claims 1-10, 13-16 and 19-29 stand rejected under 35 U.S.C. § 112, First Paragraph, as containing subject matter which was not described in the Specification in such a way as to reasonably convey to one skilled in the art that the inventor had possession of the claimed invention at the time the application was filed.

C. Claims 1-10, 13-16 and 19-29 stand rejected under 35 U.S.C. § 112, First Paragraph, as containing subject matter which was not described in the Specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

D. Claim 16 stands rejected under 35 U.S.C. § 102(b) as being anticipated by each of Kevern (U.S. Patent No. 5,850,009) and Carlone (U.S. Patent No. 5,763,755).

E. The claims do not stand or fall together. The patentability of the claims will be argued separately.

VII. ARGUMENT

A. Claims 19-24 Are Definite Under 35 U.S.C. § 112, Second Paragraph

The Examiner rejects claims 19-24 as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Applicant believes that the Examiner's rejections are improper and that the claims 19-24 are definite for several different reasons, described in detail *infra*. Importantly, this Board has already determined that claims similar to Applicant's claims 19-24 are allowable. *See Ex parte William D. Griffith*, Appeal No. 2004-1968; *Ex parte Frances L. Garing*, Appeal No. 2004-2343; and *Ex parte Thomas B. Carlson*, Appeal No. 2004-2317.

1. Claims 19 and 23-24 are Definite

The Examiner states the claims "are indefinite in their recitation of 'plant of claim 11 . . . further defined as comprising' which is confusing, as the claimed plant is simultaneously being characterized as being the plant of claim 11, which has a particular and finite genotype, as well as being a plant with an additional transgene or single locus conversion." (*See* October 14, 2005 Office Action, p. 2).

One of ordinary skill in the art would understand that what is being claimed is a single locus conversion of PH4GP. Except for the difference conferred by the inserted transgene or single locus trait, the plants and seeds of claims 19-24 will exhibit the same physiological and morphological characteristics as PH4GP. The Specification describes PH4GP as having multiple physiological and morphological traits which are readily

identifiable. (*See* Table 1, Specification pp. 18-20; Tables 2A-2B, Specification p. 38-40).

Backcrossing has been utilized routinely in maize breeding to introduce a single transgene into elite germplasm. As stated in Ragot *et al.,* "Backcrossing has been a common breeding practice for as long as elite germplasm has been available. It has mainly been used to introgress single Mendelian traits, such as disease resistances or quality factors, into elite germplasm (Allard 1960; Hallauer and Miranda 1981). One of the most attractive attributes of backcrossing is that it allows [the breeder] to perform targeted modifications without disrupting the existing overall genetic balance of the recurrent parent". (Ragot, p. 45).

In *The Beachcombers, International, Inc.*, the court stated "[t]he operative standard for determining whether this requirement has been met is whether those skilled in the art would understand what is claimed when the claim is read in light of the specification". *The Beachcombers, International, Inc., v. Wildewood Creative Products*, 31 F.3d 1154, 1158, 31 U.S.P.Q2d 1653 (Fed. Cir. 1994). Since the scope of the claimed subject matter is clear to one of ordinary skill in the art, claims 19 and 23-24 are not indefinite. *See* MPEP § 2173.04.

Applicant therefore submits that claims 19 and 23-24 are definite under 35 U.S.C. § 112, Second Paragraph.

2. Claim 22 is Definite

The Examiner states the claim is "indefinite in its recitation of 'yield enhancement' and 'improved nutritional quality', since these are relative terms, and no standard of

comparison or degree of improvement/enhancement has been recited or identified". (*See* October 14, 2005 Office Action, p. 3).

Applicant notes that "improved nutritional quality" would represent an improvement in the nutritional quality versus another variety as described on page 22 of the Specification. Here, the Specification describes the relative terms in a manner that would be well understood by one skilled in the art. To make such a determination, one would compare the nutritional quality of a single locus conversion of PH4GP with PH4GP to determine whether nutritional quality has been enhanced.

Similarly, Applicant notes that the term "Yield Advantage" is defined on page 15 of the Specification as "the yield advantage of variety #1 over variety #2". Therefore yield enhancement would be the improvement of the trait yield over another variety. Such yield advantage would be determined by comparing the yield of PH4GP with the single locus conversion of PH4GP.

It is noted that the terms would be understood by those of skill in the art and there is no prohibition upon the use of relative terms. The terms must be read in the context of the claim in which they are found. The subject claim recites a single locus that confers the traits of "improved nutritional quality" and "yield enhancement". It is thus understood the enhancement of yield and improved nutritional quality is relative to a PH4GP plant lacking the single locus. The metes and bounds of the claim are thus fully understood by one of skill in the art and the use of these terms is not indefinite. Accordingly, Applicant submits that one of ordinary skill in the art would understand what is being claimed, and claim 22 is definite under 35 U.S.C. § 112, Second Paragraph.

B. The Written Description Rejection Has Been Improperly Maintained

The Examiner rejects claims 1-10, 13-16 and 19-29 as failing to comply with the written description requirement. The Examiner states the "claims are broadly drawn to any F1 hybrid produced by crossing a single inbred parent PH4GP with any of a multitude of unspecified second parents, wherein half of the genetic composition of the hybrid is contributed by the first inbred parent" ...and ... "the specification only provided guidance for the traits exhibited by the single inbred parent PH4GP, and for traits exhibited by crossing a single inbred parent PH4GP with one other inbred parents (see Tables 3A-3B and 4). The Examiner further states that "[n]o guidance is provided regarding the genetic composition of any of a multitude of non-exemplified inbreds or hybrids at any single locus or on any chromosome." (*See* February 23, 2005 Office Action, pp. 3-4). The Examiner further rejects claims 13-16 and 19-29 for the above-stated reasons, and states that new claims 13-16 also encompass F1 hybrids, while new claims 19-30 encompass any plant produced by crossing the exemplified inbred with any uncharactertized second plant for one or more generations. (*See* October 14, 2005 Office Action, pp. 3-4).

Applicant believes that the Examiner's rejections are improper and that the written description requirement has been satisfied for several different reasons, described in detail *infra.*

1. <u>The Law of Written Description</u>

The written description requirement has been satisfied if one skilled in the relevant art would recognize that the Applicant had possession of the invention at the

time the application was filed. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 U.S.P.Q.2d 1111, 1117 (Fed. Cir. 1991); *Wang Labs, Inc. v. Toshiba, Corp.*, 993 F.2d 858, 865, 26 U.S.P.Q.2d 1767, 1774 (Fed. Cir. 1993). In essence, "the description must clearly allow persons of ordinary skill in the art to recognize that [the Applicant] invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 U.S.P.Q.2d 1614, 1618 (Fed. Cir. 1989). The Federal Circuit has recently characterized the purpose of the written description requirement as to "ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification." *Reiffin v. Microsoft Corp.*, 214 F.3d 1342, 1345, 54 U.S.P.Q.2d 1915, 1917 (Fed. Cir. 2000).

For inventions similar to Applicant's, the Federal Circuit has held that deposit in the ATCC constitutes an adequate description sufficient to comply with the written description requirement of § 112, ¶ 1. *Enzo Biochem, Inc. v. Gen-Probe Inc.,* 323 F.3d 956, 965, 63 U.S.P.Q.2d 1609, 1613-14 (Fed. Cir. 2002). The Board of Patent Appeals & Interferences has also confirmed the sufficiency of a deposit for seed and plants in the case of *Ex Parte C,* 1992 WL 515817 P. * 5, 27 U.S.P.Q.2d 1492, 1496 (Bd. Pat. App. & Interf. 1992), where it stated that "[t]he claimed soybean is described in the specification to the extent that there is no question that appellant was in possession of the invention as of the time the instant application was filed. Because seed is to be deposited in a public depository, the specification is enabling and sets forth the best mode of carrying out the invention."

In order to satisfy the written description requirement, an Applicant "[is] not required to disclose every species encompassed by their claims even in an unpredictable

art". *Regents of University of California v. Eli Lilly,* 119 F.3d 1559, 1569, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997) (citing as analogous argument *In re Angstadt*, 537 F.2d 498, 502-03, 190 U.S.P.Q.2d 214, 218 (Cust. & Pat. App. 1976)). Consistent with this principal, The Board of Patent Appeals & Interferences, in a case involving the written description requirement as applied to seed and plants, stated "[i]f in making the latter comment the examiner is requiring appellants to have reduced to practice each possible plant within the scope of the claims, such a position is legally incorrect. The specification need only teach one skilled in the art how to make and use the claimed invention. How the specification does so, whether by way of the written word or actual examples, is of no moment." *Ex parte Gerardu C.M. Bentvelsen et al.*, 2001 WL 1197757, p. *2 (Bd. Pat. App. & Interf. 2001).

The U.S. Supreme Court acknowledged in dicta the possibility that a claim to the genus of F1 hybrids can be covered in a patent to an inbred. *J.E.M. Ag. Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 143, 122 S.Ct. 593, 604, 60 U.S.P.Q.2d 1865, 1873 (2001). The Court stated therein that "...a utility patent on an inbred plant line protects the line as well as all hybrids produced by crossing that inbred with another plant line." *J.E.M. Ag. Supply, Inc.* 534 U.S. at 143, 122 S.Ct. at 604, 60 U.S.P.Q.2d at 1873.

In addition to description by structure, the written description requirement may be satisfied by disclosing functional characteristics where there is a correlation between structure and function. The Federal Circuit has stated that the written description requirement may be met by "show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics . . . i.e., complete or partial structure, other physical and/or chemical properties, *functional characteristics when*

coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." *Enzo Biochem, Inc.*, 323 F.3d at 964, 63 U.S.P.Q.2d at 1613 (quoting and adopting the USPTO's Written Description Guidelines, 66 Fed. Reg. 1106, No. 4 (2001)).

2. The Examiner's Conclusion of Lack of Written Description is Based on an Incorrect Application of the Law to the Claimed Invention

a. Maize seed, plants and plant parts encompassed by Applicant's claims 1-6, 13-16 and 7-10 have been fully described

i. The maize seed, plants, and plant parts of claims 1-6 and 13-16 have been described

Rejected claims 1-6 are directed to maize seed, plants and plant parts comprising at least one set of the chromosomes of maize inbred line PH4GP and claims 13-16 are directed to maize seed, plants and plant parts which are produced by crossing a first parent maize plant with a second parent maize plant wherein one or both of the first or the second parent maize plants is the plant of claim 11, wherein at least one of the maize parent plants is a maize plant having all the physiological and morphological characteristics of PH4GP and where a sample of PH4GP was deposited with the ATCC. Applicant's note that claims 11 and 12 from which claims 13-16 depend from have been allowed by the Examiner.

This Board has already determined that claims substantially similar to Applicant's claims have fulfilled the written description requirement. In so doing, The Board considered arguments similar to the Examiner's and ultimately concluded that the appealed claims were allowable. *See Ex parte William D. Griffith*, Appeal No. 2004-

1968; *Ex parte Frances L. Garing*, Appeal No. 2004-2343; and *Ex parte Thomas B. Carlson*, Appeal No. 2004-2317.

An inbred maize plant is primarily used for the development and production of an F1 hybrid maize plant. A single cross F1 hybrid is a maize plant which is the result of a cross between two inbred plants. (*See* Specification, p. 3, l. 20-p. 7, l. 13). Due to the genetic nature of the inbred, an F1 hybrid produced from the cross of two inbreds will always be the same. (*See* Specification, p. 4, l. 31-p. 7, l. 13).

The written description requirement may be fulfilled by identifying a structural feature which is present in each member of a claimed genus. *Regents of University of California*, 119 F.3d at 1568, 43 U.S.P.Q.2d at 1406 (teaching that claims may satisfy the written description requirement where they disclose "structural features commonly possessed by members of the genus that distinguish them from others.") The maize seeds, plants and plant parts of claims 1-6 and 13-16 all share the same genetic component and/or cells received from inbred parent PH4GP. Applicant has prepared a diagram, attached herewith as Exhibit 1, which is a visual representation of the fact that most of the cells in a maize inbred will have two essentially duplicate sets of ten chromosomes. (For illustrative purposes the ten chromosomes are represented by three rectangles in the Exhibits). In order to produce an F1 hybrid, the inbred will produce a haploid cell, such as pollen or an ovule. These haploid cells receive one copy of the inbred's duplicate sets of chromosomes. Accordingly, the F1 hybrid seed receives one complete set of chromosomes from the inbred parent, regardless of whether the inbred is used as the male or female parent of the F1 hybrid. (*See* Exhibits 2 and 3).

As known by one skilled in the art, the reason an F1 hybrid produced from an inbred maize line will always receive one complete set of chromosomes from the inbred parent is because the genome of a maize inbred line is homozygous. This homozygosity is a consequence of self pollination that occurs during the inbreeding process. As described in the Specification:

> The inbred has shown uniformity and stability within the limits of environmental influence for all the traits as described in the Variety Description Information (Table 1) that follows. The inbred has been self-pollinated and ear-rowed a sufficient number of generations with careful attention paid to uniformity of plant type to ensure the homozygosity and phenotypic stability necessary to use in commercial production. The line has been increased both by hand and in isolated fields with continued observation for uniformity. No variant traits have been observed or are expected in PH4GP. (Specification, p. 17, ll. 24-30).

Applicant reiterates the present invention relates to hybrid seed and plants which are produced by crossing inbred maize line PH4GP with another maize plant. As described *infra*, each member of the genus of hybrids which has PH4GP as a parent and which is encompassed by claims 1-6 and 13-16 comprises a set of the chromosomes of inbred line PH4GP.

The Examiner further cites *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991) "where it is taught that a gene is not reduced to practice until the inventor can define it by 'its physical or chemical properties'". (*See* February 23, 2005, Office Action, p. 4). Applicant's invention is consistent with the principle set forth in *Amgen, Inc.* The genetic marker profile of the set of chromosomes of PH4GP that will be retained in an F1 hybrid made with PH4GP can be obtained from the deposited seed, and are disclosed in the genetic (SSR) marker profile in the copending parent application U. S. Patent No. 6,720,487 which one of

ordinary skill in the art has access to.[1] (*See* U.S. Patent No. 6,720,487; Table A, column 12, l. 4 through column 13, l. 51). These molecular markers allow one of ordinary skill in the art to distinguish a maize plant containing a set of chromosomes of PH4GP from other maize plants.

An invention may be defined by "whatever characteristics sufficiently distinguish it." *Amgen*, 927 F.2d at 1200, 1206, 18 U.S.P.Q.2d at 1021 (Fed. Cir. 1991). Here, Applicant has chosen to describe the subject matter of claims 1-6 as maize seed, plants and plant parts comprising at least one set of the chromosomes of PH4GP. Claims 13-16 are described as maize seed, plants and plant parts which are produced by crossing a first parent maize plant with a second parent maize plant, where at least one of the maize parent plants is PH4GP or an equivalent maize plant having all the physiological and morphological characteristics of PH4GP of allowable claim 11. By virtue of their method of production, the plants of claims 13-16 will also comprise at least one set of the chromosomes of PH4GP.

As noted previously, The Board of Patent Appeals & Interferences has already determined that where an inbred maize plant had been deemed allowable, claims to the F1 hybrid seed and plants resulting from a cross between the allowable inbred maize plant and another inbred maize plant satisfied the written description requirement. *See Ex parte Carlson* (Bd. Pat. App. & Interf. 2005). The Board therein stated:

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[1] Applicant wishes to point out the prosecution history relevant to Table A of copending parent application, U.S. Patent No. 6,720,487. In an Amendment dated March 11, 2003, Applicant amended the Specification to include the SSR profile of Table A (*See* March 11, 2003 Amendment, p. 18). The Examiner then objected to the amendment to include Table A as new matter. (*See* May 23, 2003 Office Action, p. 6). Applicant next objected to the Examiner's rejection, but for the purposes of expediting prosecution canceled the amendment adding the Table at the Examiner's request. (*See* August 22, 2003 Amendment After Final, p. 6). The SSR profile included in Table A was then disclosed by the PTO in the published parent patent, making it available to one of ordinary skill in the art for both U.S. Patent No. 6,720,487 and the present application.

> All that is required by the claims is that the hybrid has one parent that is a plant of corn variety [inbred]. Since the examiner has indicated that the seed and the plant of the corn variety [inbred] are allowable . . . there can be no doubt that the Specification provides and adequate written description of this corn variety. In addition, the examiner appears to recognize (Answer, page 25) that appellant's Specification describes an exemplary hybrid wherein one parent was a plant of the corn variety [inbred]. . . Accordingly, it is unclear to this merits panel what additional description is necessary. *Ex parte Carlson*, p. 16.

In the present case, Applicant has similarly complied with the written description requirement. Applicant has fulfilled the written description requirement of § 112, ¶ 1 by depositing representative seeds of maize line PH4GP in the ATCC depository as deposit number PTA-4430 and by referencing the deposit in the Specification (p. 45, ll. 2-28). The maize seed and plants of inbred line PH4GP have already been deemed allowable. *See* U.S. Patent No. 6,720,487. Applicant has provided example in Tables 3A-3B and 4 of F1 hybrid combinations made with PH4GP whose F1 hybrid seed and plants were reduced to practice as of the filing date. (*See* Specification, Tables 3A-3B and 4, pp. 41-44). This represents an actual reduction to practice of the claimed invention in accordance MPEP, § 2163(II)(A)(3)(a)(ii) and is indistinguishable from the analogous facts of *Ex parte Carlson.*

The Examiner further contends that "it is even less likely that the court in *Enzo* would deem F1 hybrids to be adequately described by deposit of one inbred parent which potentially differs from the second parent at every genetic locus." (*See* October 14, 2004 Office Action, p. 7). As described *infra*, each member of the genus of hybrids which has PH4GP as a parent and which is encompassed by claims 1-6 and 13-16 shares the identifying structural feature of comprising a set of chromosomes of inbred line PH4GP. One of skill in the art, utilizing technology well known in the art, could identify any member of the claimed genus, and could distinguish an F1 hybrid made with PH4GP as a

parent from an F1 hybrid not made with PH4GP as a parent. This is sufficient to meet the written description requirement. *See Regents of University of California*, 119 F.3d at 1568, 43 U.S.P.Q.2d at 1406.

For the above reasons, a person skilled in the art would recognize that Applicant was in possession of the F1 hybrid maize seed, plants and plant parts of claims 1-6 and 13-16.

ii. The hybrid maize seed and plants of claims 7-10 have been described

Rejected claims 7-10 are directed towards F1 hybrid maize seed and plants comprising an inbred maize plant cell of inbred maize line PH4GP. These claims are adequately described for all the reasons stated *supra* in the Argument section C.2.a.i, as well as for the reasons stated below. Applicant would also like to point out that claim 17 of the instant application has been allowed, which is directed toward a cell of the maize plant of claim 11. Furthermore, claims directed towards an F1 hybrid maize seed and plants comprising an inbred maize plant cell have already been deemed allowable by this Board and the Examiner of those cases. *See Ex parte William D. Griffith*, Appeal No. 2004-1968; *Ex parte Frances L. Garing*, Appeal No. 2004-2343; and *Ex parte Thomas B. Carlson*, Appeal No. 2004-2317.

Claims 7-10 are directed to an F1 hybrid maize seed and plants comprising an inbred maize plant cell. Pericarp tissue is a layer of tissue (cells) surrounding the outside of maize seed, which can be peeled and analyzed. One of ordinary skill in the art would know that the pericarp tissue of an F1 hybrid seed comprises intact plant cells of the maternal parent. Thus, an F1 hybrid seed created with PH4GP as the maternal parent will

have pericarp tissue comprising a plant cell of PH4GP, and this plant cell is genetically identical to cells of inbred maize line PH4GP present in the seed deposit. The written description requirement is fulfilled where a structural feature is identified which is present in each member of a claimed genus. *Regents of University of California*, 119 F.3d at 1568, 43 U.S.P.Q.2d at 1406.

Accordingly, a person skilled in the art would recognize that Applicant was in possession of F1 hybrid maize seed, plants and plant parts comprising at least one PH4GP cell. As further specified in claim 9, this cell would comprise two sets of the chromosomes of PH4GP (*See* Exhibit 1). Therefore, claims 7-10 are adequately described by the Specification.

b. The maize plants having all the physiological and morphological traits of PH4GP and a single locus conversion and/or transgene encompassed by Applicant's claims 19-24 have been fully described

Rejected claims 19-24 are directed towards a maize plant having all the physiological and morphological characteristics of inbred line PH4GP of allowable claim 11, wherein the seed of PH4GP was deposited with the ATCC and wherein the maize plants have a genome comprising a single locus conversion and/or transgene such as herbicide tolerance; insect resistance; resistance to bacterial, fungal, or viral disease; yield enhancement; waxy starch; improved nutritional quality; male sterility and restoration of male fertility. Claims 19-24 ultimately depend from allowed claim 11.

This Board has already determined that claims substantially similar to Applicant's claims 19-24 were allowable and fulfilled the written description requirement. *See Ex parte William D. Griffith*, Appeal No. 2004-1968; *Ex parte Frances L. Garing*, Appeal

No. 2004-2343; and *Ex parte Thomas B. Carlson*, Appeal No. 2004-2317. Despite this fact, the Examiner rejects claims 19-24 as failing to meet the written description requirement and states the claims "encompass any plant produced by crossing the exemplified inbred with any uncharacterized second plant for one or more generations." (*See* October 14, 2005 Office Action, p. 4).

As Applicant has demonstrated *supra*, the Specification describes the physiological and morphological traits of PH4GP. (*See* Table 1, Specification pp. 18-20; Tables 2A-2B, Specification pp. 38-40). Applicant further describes a single locus conversion refers to the introgression of a trait governed by a single locus into a maize plant. (*See* Specification, p. 21, ll. 16-31; p 28, l. 23 - p. 33, l. 6). Applicant asserts that the terms "single gene conversion" and "single locus conversion" are synonymous and would be well understood by one of ordinary skill in the art. The Specification provides multiple examples of transgenes and other single locus conversions conferring specific traits which can be added to PH4GP. (*See* Specification, p. 21, ll. 16-31; p 28, l. 23 - p. 33, l. 6). For example, the Specification describes traits, such as "waxy starch, nutritional enhancements, industrial enhancements, disease resistance, insect resistance, herbicide resistance and yield enhancements" for which the appropriate genes may be backcrossed into PH4GP. (Specification, p. 21, ll. 21-23). Further, and for purposes of example only, the Specification describes over four pages of exemplary transgenes which may be added to PH4GP. (*See* Specification, p. 28, l. 23 - p. 33, l. 6). In order to satisfy the written description requirement, an Applicant "[is] not required to disclose every species encompassed by their claims even in an unpredictable art". *Regents of University of California,* 119 F.3d at 1569, 43 U.S.P.Q.2d at 1406.

The Specification also describes how to backcross traits into PH4GP. (*See* Specification, p. 21, ll. 16-31). The Specification states:

> Backcrossing can be used to transfer a specific desirable trait from one inbred or source to an inbred that lacks that trait. This can be accomplished, for example, by first crossing a superior inbred (recurrent parent) to a donor inbred (non-recurrent parent), that carries the appropriate gene(s) for the trait in question. The progeny of this cross is then mated back to the superior recurrent parent followed by selection in the resultant progeny for the desired trait to be transferred from the non-recurrent parent." (Specification, p. 4, ll. 11-17).

Furthermore, the Specification teaches multiple ways of introgressing or transforming a maize plant with various genes which encode specific protein products which confer advantageous traits desired in the plant. (*See* Specification, p. 22, l. 33-p. 35, l. 4). This includes the use of markers to aid in the identification, selection and transformation of the maize plant with the desired gene.

Backcrossing has been successfully used by corn breeders to introduce single locus traits into elite inbreds since the 1950's. Wych (1988) Production of Hybrid Seed, Corn and Corn Improvement, Ch. 9, pp. 585-586 (attached as Exhibit 4). Wych discusses how the male sterility trait is routinely backcrossed into an inbred line and how this is used to produce a sterile/fertile blend of an F1 hybrid in order to reduce seed production costs. Wych, pp. 585-586. In addition, it is currently the method used to introgress a transgene of interest into an elite inbred, and then this elite inbred comprising a single locus trait conversion is used to create F1 hybrids with the trait. The commercial market now distributes a multitude of products produced in this manner.

The ability of one of ordinary skill in the art to effectively use backcrossing to introgress a single locus conversion (a single trait conversion) is also clearly supported by the scientific literature. For example, see Ragot, M. *et al.* (1995) Marker-assisted

backcrossing: a practical example, in *Techniques et Utilisations des Marqueurs Moleculaires (Les Colloques*, Vol. 72, pp. 45-56 (attached as Exhibit 5), and Openshaw *et al.*, (1994) Marker-assisted Selection in Backcross Breeding, Analysis of Molecular Marker Data, pp. 41-43 (attached as Exhibit 6). Ragot *et al.* provides multiple demonstrations of successful backcrosses. Ragot *et al.*, Fig. 1-a - 1-d, pp. 48-52. One of ordinary skill in the art reduces linkage drag via recurrent backcrossing and molecular selection from the homozygous parent line. Accordingly, Ragot *et al.* teaches that with an inbred line, such as PH4GP, and the knowledge of one skilled in the art, single locus conversions are commonly made with little or no linkage drag.

It is understood by those of skill in the art that backcross conversions and transformations are routinely produced and do not represent a substantial change to a variety. For example, Hallauer *et al.* states that "[f]or single gene traits that are relatively easy to classify, the backcross method is effective and relatively easy to manage." Hallauer *et al.* (1988) Corn Breeding, Corn And Corn Improvement, No. 18, p. 472 (attached as Exhibit 7). The teaching of Hallauer *et al.* relates specifically to corn breeding.

Further, the World Seed Organization, on its web site, writes, "[t]he concept of an essentially derived variety was introduced into the 1991 Act of the UPOV Convention in order to avoid <u>plagiarism</u> through mutation, <u>multiple back-crossing</u> and to fill the gap between Plant Breeder's Rights and patents." ASSINSEL, an International breeders association, has published a position paper that refers to a conversion produced by repeated backcrossing of parental lines of hybrid varieties as a "cosmetic modification". As determined by the UPOV Convention, "essentially derived varieties may be obtained

for example by the selection of a natural or induced mutant, or of a somaclonal variant, the selection of a variant individual from plants of the initial variety, backcrossing, or transformation by genetic engineering" (emphasis added) (copies of web pages with these quotes are attached as Exhibit 8).

Applicant further wishes to point out that the plants and seeds of claims 19-24 must be within the scope of allowable claim 11, meaning that they must exhibit the physiological and morphological traits of PH4GP. Except for the difference conferred by the inserted transgene, the plants and seeds of claims 19-24 will exhibit the same physiological and morphological characteristics as PH4GP.

As argued *supra*, Applicant has described a plant having all the physiological and morphological traits of PH4GP. Applicant has additionally described exemplary transgenes as well as how to add these transgenes to a maize plant having all the physiological and morphological traits of PH4GP. Accordingly, an individual skilled in the art would therefore understand that Applicant was in possession of variety PH4GP, comprising a single locus conversion and/or a transgene. Claims 19-24 have been fully described.

c. The methods for producing maize plants using the plant of claim 11 encompassed by Applicant's claims 25-29 have been fully described

Rejected claims 25-29 are directed towards methods for producing or developing a maize plant which utilize a maize plant having all the physiological and morphological characteristics of inbred line PH4GP, wherein a sample of PH4GP has been deposited with the ATCC. This Board has already determined that claims similar to Applicant's claims 25-29 are allowable. *See Ex parte William D. Griffith*, Appeal No. 2004-1968; *Ex*

parte Frances L. Garing, Appeal No. 2004-2343; and *Ex parte Thomas B. Carlson*, Appeal No. 2004-2317.

The Examiner rejects claims 25-29 as failing to meet the written description requirement and states the claims "encompass any plant produced by crossing the exemplified inbred with any uncharacterized second plant for one or more generations." (*See* October 14, 2005 Office Action, p. 4). Claims 25-29 are <u>method</u> claims directed towards producing a maize plant using the plant of allowed claim 11, and are not product by process claims as the Examiner states.

PH4GP represents a novel starting material used in a variety of breeding techniques well known to an individual skilled in the art. Proper claim construction requires treating language in a method claim which recites the making or using of a nonobvious product as a material limitation. *See* MPEP § 2116.01. Because written description is measured in relation to the invention as it is claimed, the use of PH4GP in the plant breeding techniques of claims 25-29 is a limitation that must be considered for written description. *See Shatterproof Glass Corp. v. Libey-Owens Ford Co.*, 758 F.2d at 624, 225 U.S.P.Q. at 641 (Fed. Cir. 1985).

Applicant accordingly has shown that they are in possession of the novel point of claims 25-29, which is the use of PH4GP. This is sufficient to meet the written description requirement. *Vas-Cath, Inc.*, 935 F.2d at 1563-64, 19 U.S.P.Q.2d at 1117. An individual skilled in the art would understand methods for producing or developing a maize plant which utilizes PH4GP or a maize plant with all the physiological and morphological characteristics of inbred line PH4GP. Accordingly, claims 25-29 have been fully described.

3. Conclusion as to Written Description

The written description requirement has been satisfied if one skilled in the relevant art would recognize that the Applicant had possession of the invention at the time the application was filed. *Vas-Cath Inc.*, 935 F.2d at 1555, 1563, 19 U.S.P.Q.2d at 1111, 1117; *Wang Labs Inc.*, 993 F.3d at 858, 865, 26 U.S.P.Q.2d at 1774. Applicant has created a novel inbred line PH4GP, and by virtue of the deposit of PH4GP, one of ordinary skill in the art is in possession not only of PH4GP, but of a genus of F1 hybrids produced with PH4GP, transgenic and other single locus trait conversions of PH4GP, and methods of using PH4GP in further plant breeding. Applicant is entitled to the scope of their invention as claimed.

In sum, Applicant has fully satisfied the legal standards for written description as set forth in case law and the written description guidelines. Appellant therefore respectfully requests that the Examiner's rejection under 35 U.S.C. § 112, First Paragraph be reversed.

C. The Examiner has Failed To Rebut the Presumption of Enablement for Claims 1-10, 13-16 and 19-29

The Examiner rejects claims 1-10, 13-16, and 19-29 as failing to comply with the enablement requirement. The Examiner's rejections are improper for all of the reasons set forth below.

1. The Law Of Enablement

The Federal Circuit has stated:

> [A] Specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the First Paragraph of section 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.

In re Brana, 51 F.3d 1560, 1566, 34 U.S.P.Q.2d 1436,1441 (Fed. Cir. 1995), *citing, In re Marzocchi*, 439 F.2d 220, 223, 169 U.S.P.Q. 367, 369 (Cust. & Pat. App. 1971). There is thus a presumption that the Applicant's disclosure is valid. *Id.*

Enablement requires only that one of ordinary skill in the art be able to practice the claimed invention without undue experimentation. *In re Wands*, 858 F.2d 731, 737, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988). Several factors may be considered in determining whether a Specification is enabling. Although none of these factors are controlling and not all of them need be considered, they are illustrative: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *In re Wands*, 858 F.2d at 737, 8 U.S.P.Q.2d at 1404. Experimentation is permissible if it is routine and if guidance is provided directing such experimentation such that one skilled in the art would be able to practice an embodiment of the invention. *Ex parte Forman*, 230 U.S.P.Q. 546, 547 (Bd. Pat. App. & Interf. 1986).

2. <u>The Examiner's Conclusion of Lack of Non-Enablement is Based on an Inadequate Application of the Law to the Claimed Invention</u>

a. The claimed maize seed, plants and plant parts encompassed by Applicant's claims 1-10 and 13-16 have been fully enabled

The Examiner states the "claims are broadly drawn to any F1 hybrid produced by crossing a single inbred parent PH4GP with any of a multitude of unspecified second parents, wherein half of the genetic composition of the hybrid is contributed by the first inbred parent." (*See* February 23, 2005 Office Action, p. 5). This Board has already determined that claims similar to Applicant's claims 1-10 and 13-16 were allowable and fulfilled the enablement requirement. *See Ex parte William D. Griffith*, Appeal No. 2004-1968; *Ex parte Frances L. Garing*, Appeal No. 2004-2343; and *Ex parte Thomas B. Carlson*, Appeal No. 2004-2317. In addition, Applicant has described how to produce an F1 hybrid from inbred maize line PH4GP. (*See* Specification, p. 4, l. 31 -p. 7, l. 13). Applicant has made a deposit of inbred PH4GP that fully enables others to obtain the inbred seed needed to make the claimed F1 hybrids. It would be routine to cross this plant with another to produce F1 hybrid seed.

Applicant has also provided a working example showing the production of an F1 hybrid produced from the cross of inbred PH4GP and inbred PH6ME (*See* Table 4, Specification, pp. 43-44). In addition, Tables 3A-3B provides further working examples which demonstrate that inbred PH4GP performs well in a variety of F1 hybrid crosses, a characteristic referred to by corn breeders as good general combining ability.
The Examiner has shown no evidence as to why this working example does not show enablement of claims 1-10 and 13-16, directed to hybrid maize plants, plant parts and seeds produced by crossing maize inbred line PH4GP with another maize plant. One of

ordinary skill in the art could therefore use PH4GP and another maize inbred plant to create an F1 hybrid without undue experimentation. This is sufficient to enable claims 1-10 and 13-16. *In re Wands*, 858 F.2d at 737, 8 U.S.P.Q.2d at 1404.

The Examiner's reference to Kevern, U.S. Patent No. 5,850,009 (column 4, ll. 41-46) is inapposite because the section cited therein is discussing genetically segregating F2 populations of seed. By contrast, F1 hybrids, including the F1 hybrid seed and plants of claims 1-10 and 13-16, are not genetically segregating populations and any reference to Kevern is inappropriate. (*See* Exhibits 1-3, and Specification, p. 4, l. 31-p. 5, l. 16).

For these same reasons, the Examiner's citation to Carlone, U.S. Patent No. 5,763,755 is misplaced. Carlone states that "[e]ven if an inbred in hybrid combination has excellent yield, *it* may not be useful because *it* fails to have acceptable parental traits such as yield, seed size, pollen production, good silks, plant height, etc". (*See* Carlone, columns 1-2, emphasis added). The referenced section of Carlone is specifically discussing selection within the genetically segregating populations of seed that a breeder uses for **inbred** development, not F1 hybrid creation. A hybrid of the claimed invention, however, is not a genetically segregating population. Further, the patent cited by the Examiner is one in which Carlone developed a novel inbred line and was allowed claims to the hybrid seed and plants produced from the novel inbred line. Therefore, Applicant respectfully asserts the Examiner has misinterpreted the cited portion of the Carlone reference and has inappropriately applied Carlone to the present invention. The use of stable inbred lines, such as PH4GP, does enable one of ordinary skill in the art to create the claimed hybrids.

Likewise, the Examiner's citation to Stuber *et al.* is misplaced. The Examiner states that the cited reference teaches that "grain yield and ear number were strongly affected by environmental influences such as plant density, and that epistatic genetic interactions prevented accurate performance prediction of particular hybrids derived from particular crosses (see, e.g., page 503, Abstract; page 505, column 1, first and third full paragraphs; page 506, paragraph bridging the columns)". (*See* February 23, 2005 Office Action, p. 6). Stuber *et al.* is comparing synthetic populations and not F1 hybrids as taught by the present application. (See Stuber *et al.*, p. 503 under *Materials and Method*, where Stuber notes that all possible crosses, including 3-way and double crosses, were made). In contrast, the claimed invention teaches the use of stable and genetically fixed inbred lines to produce an F1 hybrid. An F1 hybrid as claimed is not a genetically mixed population, but rather is highly homogeneous and reproducible because it is made from the highly homogeneous and reproducible inbred maize line PH4GP. (*See* Specification, p. 16, lines 7-8). Thus, Applicant respectfully asserts the arguments set forth by the Examiner do not apply to the presently claimed invention.

Moreover, the Examiner's citation to Melchinger *et al.* is misplaced. The Examiner states the reference teaches "that epistatic effects reduced the amount of heterosis in hybrid crosses" (see, e.g., page 231 column 1, bottom paragraph; column 2, first paragraph of Introduction; page 223, column 2, bottom paragraph; page 237, column 1, top paragraph). (*See* February 23, 2005 Office Action, p. 6). As discussed *supra* with respect to Stuber *et al.*, Applicant asserts that Melchinger *et al.* is discussing the making of all possible crosses including F2, 3-way and backcrosses, to produce a population of seed (Melchinger, first sentence of Summary). In contrast, the claimed invention teaches

the use of a stable, genetically fixed and reproducible inbred line to produce a stable and reproducible F1 hybrid. Therefore, Applicant respectfully asserts the arguments set forth by the Examiner do not apply to the presently claimed invention.

Inbred maize lines are primarily used to produce F1 hybrid seed and plants. The claimed F1 hybrid seed is routinely and easily produced by crossing a plant from inbred maize line PH4GP with a plant from another inbred maize line. Applicant has described how to produce an F1 hybrid from inbred maize line PH4GP. (*See* Specification, p. 4, l. 31-p. 7, l. 13). Applicant has also made a deposit of inbred PH4GP that fully enables one of ordinary skill in the art to obtain the inbred seed needed to make the claimed F1 hybrids without undue experimentation. Accordingly, Applicant submits that claims 1-10 and 13-16 are fully enabled. *In re Wands*, 858 F.2d at 737, 8 U.S.P.Q.2d at 1404.

b. The claimed maize plants having all the physiological and morphological traits of PH4GP and a single locus conversion and/or transgene encompassed by Applicant's claims 19-24 have been fully enabled

Claims 19-24 are directed towards the plant of allowed claim 11 comprising a single locus conversion and/or a transgene. The Examiner has rejected these claims as failing to comply with the enablement requirement on the basis that the use of molecular markers in corn breeding is unpredictable (*See* October 14, 2005 Office Action, p. 4). In addition, in an Advisory Action, the Examiner states that the Oppenshaw *et al.* and Ragot *et al.* references support the Examiner's position that marker-assisted breeding is unpredictable (*See January 12, 2006* Advisory Action, p. 2).

This Board has already determined that claims similar to Applicant's claims 19-24 were allowable and fulfilled the enablement requirement. *See Ex parte William D.*

Griffith, Appeal No. 2004-1968; *Ex parte Frances L. Garing*, Appeal No. 2004-2343; and *Ex parte Thomas B. Carlson*, Appeal No. 2004-2317.

The Examiner cites Murray *et al.* and states that "linkage drag is common phenomenon in corn breeding and that the equivalent of 10 backcrosses resulted in the retention of 10% of the unwanted donor parent genome, in contrast to the predicted less than 1%." (*See* October 14, 2005 Office Action, p. 4). To overcome this argument, Applicant has provided references (Ragot, M. *et al.* (1995) Marker-assisted backcrossing: a practical example, in *Techniques et Utilisations des Marqueurs Moleculaires (Les Colloques*, Vol. 72, pp. 45-56, attached as Appendix 5; and Openshaw *et al.*, (1994) Marker-assisted Selection in Backcross Breeding, Analysis of Molecular Marker Data, pp. 41-43, attached as Appendix 6) which demonstrate the ability of one of ordinary skill in the art to effectively use backcrossing to introgress a single locus conversion. The Examiner interprets Ragot *et al.* as standing for the proposition that developing fully converted near isogenic lines through classical backcrossing is not possible, even when molecular markers are used (advisory action, p. 2). Applicant respectfully points out that this is a misinterpretation of Ragot *et al.*. Ragot *et al.* discuss the use of RFLP markers to assist in developing backcross conversions of maize lines, and the fact that markers allow for a quicker and more complete recovery of the recurrent parent genome. In the conclusion, Ragot *et al.* state that "only four backcross generations were necessary to recover, in less than a year and a half from planting of the BC1s, individuals which appeared to be genotypically fully converted" (p. 55). Ragot *et al.* concludes that "recovery of the recurrent parent genotype could proceed even faster than in the

experiment described herein, should the appropriate protocol and resources (population size, number and position of markers) be allocated."

Applicant notes that Murray *et al.* is a reference which is eighteen years old. Molecular marker technology (and biotechnology in general) is a rapidly changing field, and marker technology has dramatically improved since 1988. Six years later, Ragot et al. demonstrated that "spectacular" progress toward the recurrent parent genotype was obtained with 61 RFLP markers. Since that time, and at the time of the filing of this application, marker technology had further improved to the point where a large number of SSR markers were known and routinely used by those of ordinary skill in the art.

In addition, the specification provides a description of how to backcross traits into PH4GP (Specification, p. 21, ll. 16-31) and it is understood by those of skill in the art that backcross conversions are routinely produced and do not represent a substantial change to a variety. The World Seed Organization, on its web site, writes, "[t]he concept of an essentially derived variety was introduced into the 1991 Act of the UPOV Convention in order to avoid <u>plagiarism</u> through mutation, <u>multiple back-crossing</u> and to fill the gap between Plant Breeder's <u>Rights and patents</u>." ASSINSEL, an International breeders association, has published a position paper that refers to a conversion produced by repeated backcrossing of parental lines of hybrid varieties as a "cosmetic modification". Thus, it is clear that there is worldwide agreement that by obtaining the seed of a newly developed variety such as PH4GP, one of ordinary skill in the art is enabled to use such seed for repeated backcrossing in accordance with claims 19-24, and that in doing so, one may produce only a cosmetic modification and plagiarize the work of the inbred inventor.

The Examiner states that "value-added traits" are conferred by multiple genes, or quantitatively inherited (office action, p. 4). The Examiner further cites Goldman *et al.* and states that "the use of molecular markers to facilitate the identification of chromosomal regions associated with quantitatively inherited traits is hampered by the different linkage maps generated when different breeding lines are used as parents." (*See* October 14, 2005 Office Action, pp. 4-5). The Examiner's citation of Goldman *et al.* is misplaced. Goldman *et al.* is discussing quantitative multigenic traits, whereas the instant application claims a single locus conversion. The Examiner again cites Murray *et al.* and references page 79 as support for the argument that the use of molecular markers is unpredictable. However, the paragraph cited by the Examimer discusses identification of RFLP marker alleomorphs conserved across maize lines which is unrelated to the use of markers for developing a single locus conversion. Applicant re-emphasizes that a single locus conversion is the subject matter claimed in the instant application.

As described *supra*, the Specification provides multiple examples of transgenes and other single locus conversions as well as a description of how to backcross genes governing desired traits into PH4GP. (*See* Specification, p. 21, ll. 16-31; p 28, l. 23 - p. 33, l. 6). This includes the use of markers to aid in the identification, selection and transformation of the maize plant with the desired gene. In addition, as discussed *supra*, commercial development of hybrid maize lines commonly encompasses the use of introgression to produce a single locus conversion from novel elite inbred lines and is well known to one skilled in the art. Accordingly, claims 19-24 are enabled.

c. The claimed maize seed and plants having all the physiological and morphological traits of PH4GP and methods for making the same encompassed by Applicant's claims 25-29 have been fully enabled

Rejected claims 25-30 are directed towards methods for producing or developing a maize plant which utilize a maize plant having all the physiological and morphological characteristics of inbred line PH4GP, wherein a sample of PH4GP has been deposited with the ATCC. This Board has already determined that claims similar to Applicant's claims 25-29 were allowable and fulfilled the enablement requirement. *See Ex parte William D. Griffith*, Appeal No. 2004-1968; *Ex parte Frances L. Garing*, Appeal No. 2004-2343; and *Ex parte Thomas B. Carlson*, Appeal No. 2004-2317.

Claims 25-29 are method claims directed towards producing a maize plant using the plant of allowable claim 11. As discussed *supra*, the citations of Murray *et al.* and Goldman *et al.* by the Examiner are misplaced. As discussed *supra*, claim 11, which is not rejected by the Examiner, is enabled. The Examiner has provided no reason as to why claims 25-29, which depend from claim 11, are not as well.

PH4GP represents a novel starting material used in a conventional process. These methods are clearly described in the claims and in the Specification, and involve standard plant breeding techniques well known to one of ordinary skill in the art of plant breeding. Through the deposit of PH4GP and description of the steps in claims 25-29, one of ordinary skill in the art would well know how to make and use the invention as claimed, and would be greatly advantaged to use PH4GP as starting material in a plant breeding program intended to develop lines with the phenotypic advantages of PH4GP disclosed in the Specification. Claims 25-29 are therefore fully enabled. *In re Wands*, 858 F.2d at 737, 8 U.S.P.Q.2d at 1404.

3. Conclusion as to Enablement

Applicant has fully enabled others to produce F1 hybrids from inbred maize line PH4GP. Applicant has deposited seed of PH4GP with a public depository, the ATCC. The Specification and the cited scientific literature teach that backcrossing a transgene or other single locus trait into an inbred line is routine. Furthermore, Applicant teaches in the Specification, and one skilled in the art would know, how to use novel inbred line PH4GP in a maize plant breeding program.

Upon the expiration of the patent, PH4GP will be available to the public to use directly to produce F1 hybrids, to produce transgenic and other single locus conversions, and to use as breeding material to make progeny lines. The public will obtain the benefit of the invention within the scope claimed, and the quid pro quo for patent protection will have been satisfied. Applicant has thus fully satisfied the legal standards for enablement, and respectfully requests that the Examiner's rejection under 35 U.S.C. § 112, First Paragraph be reversed.

D. The Examiner's Rejection of Claim 16 Under 35 U.S.C. § 102(b) is Improper

The Examiner rejects claim 16 as being anticipated by each of Kevern (U.S. Patent No. 5,850,009) and Carlone (U.S. Patent No. 5,763,755). The Examiner states that because the claim is drawn to F2 seeds "the claims read on any plant of any genotype, including those taught by each of Kevern and Carlone." (*See* October 14, 2005 Office Action, p. 5).

Applicant asserts that the claimed F2 maize seed is a plant part of the F1 hybrid plant, and is physically attached to the F1 hybrid plant after seed formation. Even when

removed from the F1 hybrid plant, the F2 maize seed retains the pericarp. The pericarp of the F2 grain would be from the F1 hybrid, which will comprise one set of the chromosomes of the inbred. Therefore an F2 hybrid seed produced on an F1 plant where PH4GP is a parent will contain a structural feature of PH4GP present in the ATCC deposit of PH4GP.

Neither Kevern nor Carlone disclose each of the limitations of claim 16. Claim 16 is drawn to an F2 maize seed, which is produced by growing the F1 maize plant of claim 15 and harvesting the resultant maize seed. The F1 maize plant of claim 15 is produced from the hybrid seed of claim 14, which ultimately depends from allowed claim 12.

Furthermore, neither Kevern nor Carlone teach the seed or plant of PH4GP deposited under ATCC Accession No. PTA-4430, or an F1 seed or plant produced from PH4GP. Therefore, because neither Kevern nor Carlone teaches PH4GP, neither can anticipate claim 16. Accordingly, Applicant submits that claim 16 is not anticipated by Kevern (U.S. Patent No. 5,850,009) and Carlone (U.S. Patent No. 5,763,755).

For the above-stated reasons, it is submitted that the claims are in condition for allowance. The decision of the Examiner, therefore, should be reversed and the case allowed.

Enclosed herein please find the appeal brief and required fee of $500. If this amount is not correct, please consider this a request to debit or credit Deposit Account No. 26-0084 accordingly.

Respectfully submitted,

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VIII. CLAIMS APPENDIX

Claim 1: A seed comprising at least one set of the chromosomes of maize inbred line PH4GP, representative seed of said line having been deposited under ATCC Accession No. PTA-4430.

Claim 2: A maize plant produced by growing the seed of claim 1.

Claim 3: A maize plant part of the maize plant of claim 2.

Claim 4: An F1 hybrid maize seed produced by crossing a plant of maize inbred line designated PH4GP, representative seed of said line having been deposited under ATCC Accession No. PTA-4430, with a different maize plant and harvesting the resultant F1 hybrid maize seed, wherein said F1 hybrid maize seed comprises two sets of chromosomes and one set of the chromosomes is the same as maize inbred line PH4GP.

Claim 5: A maize plant produced by growing the F1 hybrid maize seed of claim 4.

Claim 6: A maize plant part of the maize plant of claim 5.

Claim 7: An F1 hybrid maize seed comprising an inbred maize plant cell of inbred maize line PH4GP, representative seed of said line having been deposited under ATCC Accession No. PTA-4430.

Claim 8: A maize plant produced by growing the F1 hybrid maize seed of claim 7.

Claim 9: The F1 hybrid maize seed of claim 7 wherein the inbred maize plant cell comprises two sets of chromosomes of maize inbred line PH4GP.

Claim 10: A maize plant produced by growing the F1 hybrid maize seed of claim 9.

Claim 11: A maize plant having all the physiological and morphological characteristics of inbred line PH4GP, wherein a sample of the seed of inbred line PH4GP was deposited under ATCC Accession Number PTA-4430. ALLOWED

Claim 12: A process of producing maize seed, comprising crossing a first parent maize plant with a second parent maize plant, wherein one or both of the first or the second parent maize plants is the plant of claim 11, wherein seed is allowed to form. ALLOWED

Claim 13: The maize seed produced by the process of claim 12.

Claim 14: The maize seed of claim 13, wherein the maize seed is hybrid seed.

Claim 15: A hybrid maize plant, or its parts, produced by growing said hybrid seed of 14.

Claim 16: A maize seed produced by growing said maize plant of claim 15 and harvesting the resultant maize seed.

Claim 17: A cell of the maize plant of claim 11. ALLOWED

Claim 18: A seed comprising the cell of claim 17. ALLOWED

Claim 19: The maize plant of claim 11, further defined as having a genome comprising a single locus conversion.

Claim 20: The maize plant of claim 19, wherein the single locus was stably inserted into a maize genome by transformation.

Claim 21: The maize plant of claim 19, wherein the locus is selected from the group consisting of a dominant allele and a recessive allele.

Claim 22: The maize plant of claim 19, wherein the locus confers a trait selected from the group consisting of herbicide tolerance; insect resistance; resistance to bacterial, fungal, or viral disease; yield enhancement; waxy starch; improved nutritional quality; male sterility and restoration of male fertility.

Claim 23: The maize plant of claim 11, wherein said plant is further defined as comprising a gene conferring male sterility.

Claim 24: The maize plant of claim 11, wherein said plant is further defined as comprising a transgene conferring a trait selected from the group consisting of male sterility, herbicide resistance, insect resistance, and disease resistance.

Claim 25: A method of producing a maize plant derived from the inbred line PH4GP, the method comprising the steps of:

(a) growing a progeny plant produced by crossing the plant of claim 11 with a second maize plant;

(b) crossing the progeny plant with itself or a different plant to produce a seed of a progeny plant of a subsequent generation;

(c) growing a progeny plant of a subsequent generation from said seed and crossing the progeny plant of a subsequent generation with itself or a different plant; and

(d) repeating steps (b) and (c) for an additional 0-5 generations to produce a maize plant derived from the inbred line PH4GP.

Claim 26: The method of claim 25, wherein the maize plant derived from the inbred line PH4GP is an inbred maize plant.

Claim 27: The method of claim 26, further comprising the step of crossing the inbred maize plant derived from the inbred line PH4GP with a second, distinct inbred maize plant to produce an F1 hybrid maize plant.

Claim 28: A method for developing a maize plant in a maize plant breeding program using plant breeding techniques comprising employing a maize plant, or its parts, as a source of plant breeding material comprising using the maize plant of claim 11, or parts thereof, as a source of said breeding material.

Claim 29: The method for developing a maize plant in a maize plant breeding program of 28 wherein plant breeding techniques are selected from the group consisting of recurrent selection, backcrossing, pedigree breeding, restriction fragment length polymorphism enhanced selection, genetic marker enhanced selection, and transformation.

IX. EVIDENCE APPENDIX

Only evidence of record has been relied upon in this appeal.

Exhibit 1: Diagram prepared by Applicant

First cited by Applicant in May 19, 2005 Amendment, p. 6. The Examiner's October 14, 2005 Office Action was entered in response to this Amendment.

Chromosomal View of Inbred PH4GP

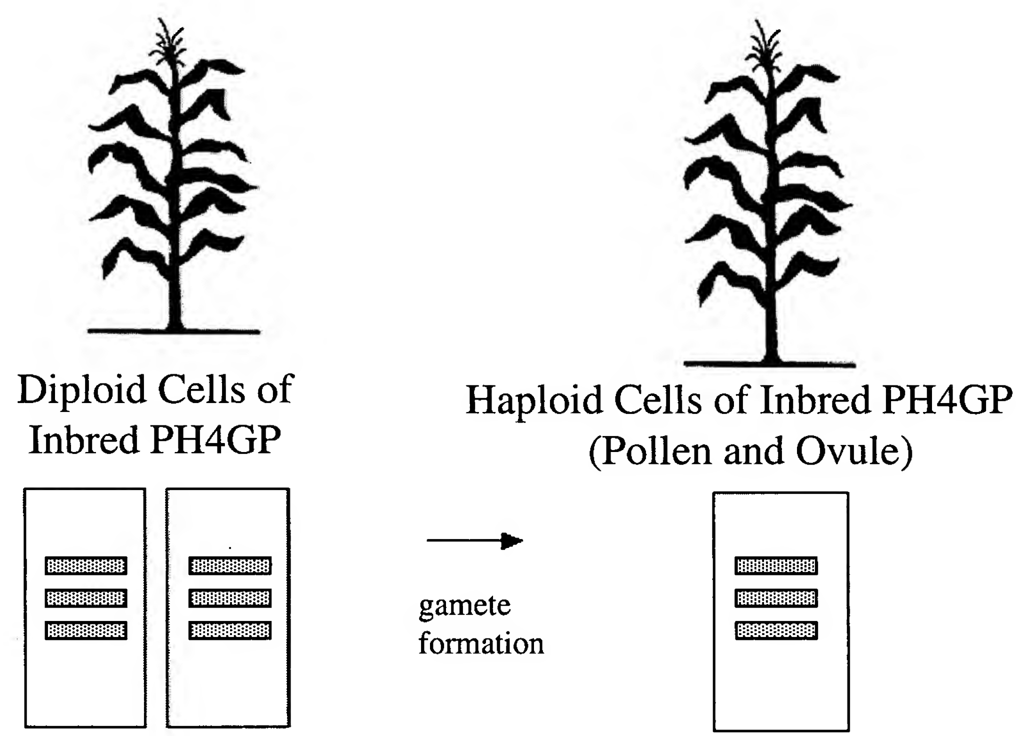

Exhibit 2: Diagram prepared by Applicant

First cited by Applicant in May 19, 2005 Amendment, p. 6. The Examiner's October 14, 2005 Office Action was entered in response to this Amendment.

F1 Hybrid corn seed and plants: PH4GP as Male Parent

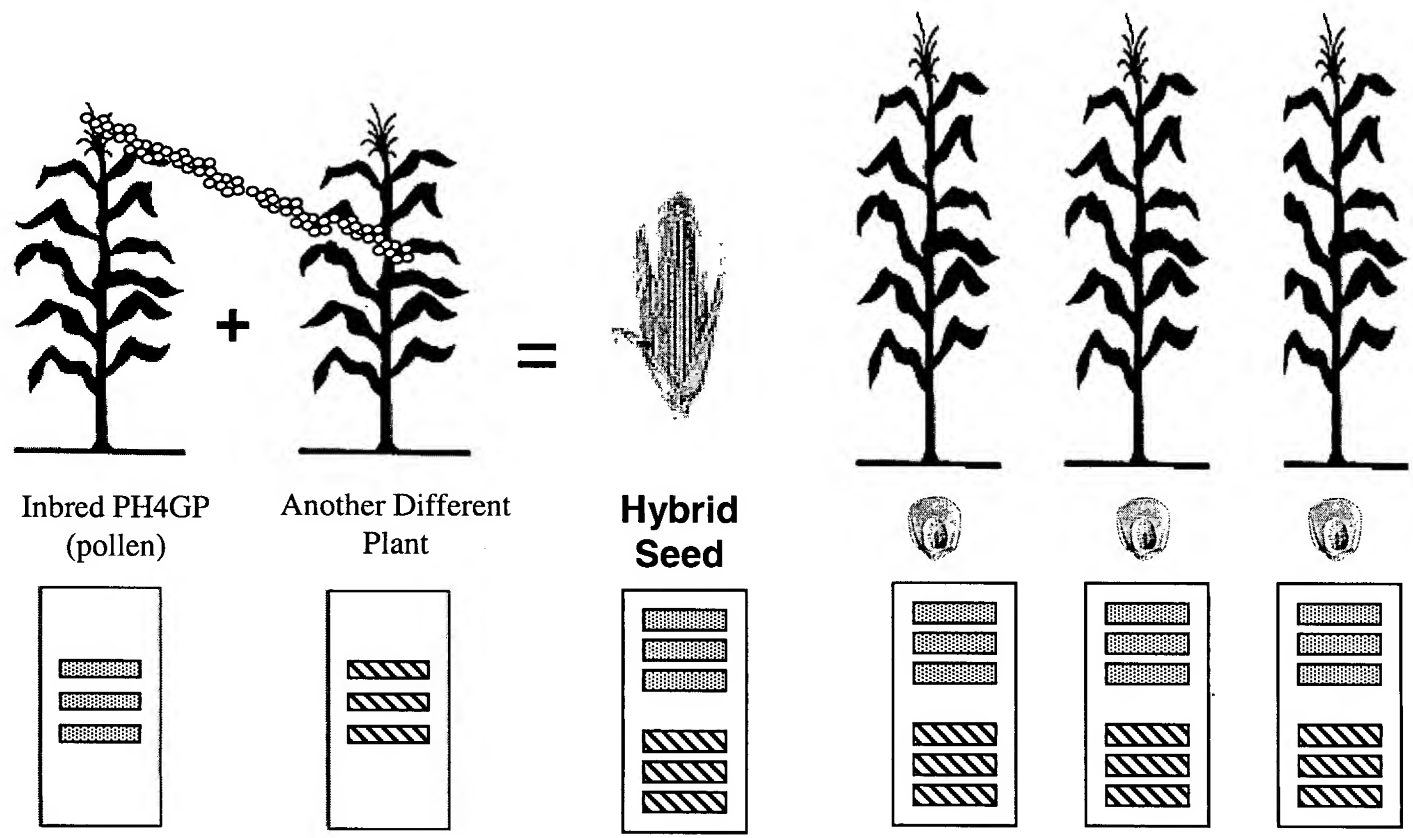

Exhibit 3: Diagram prepared by Applicant

First cited by Applicant in May 19, 2005 Amendment, p. 6. The Examiner's October 14, 2005 Office Action was entered in response to this Amendment.

F1 Hybrid corn seed and plants: PH4GP as Female Parent

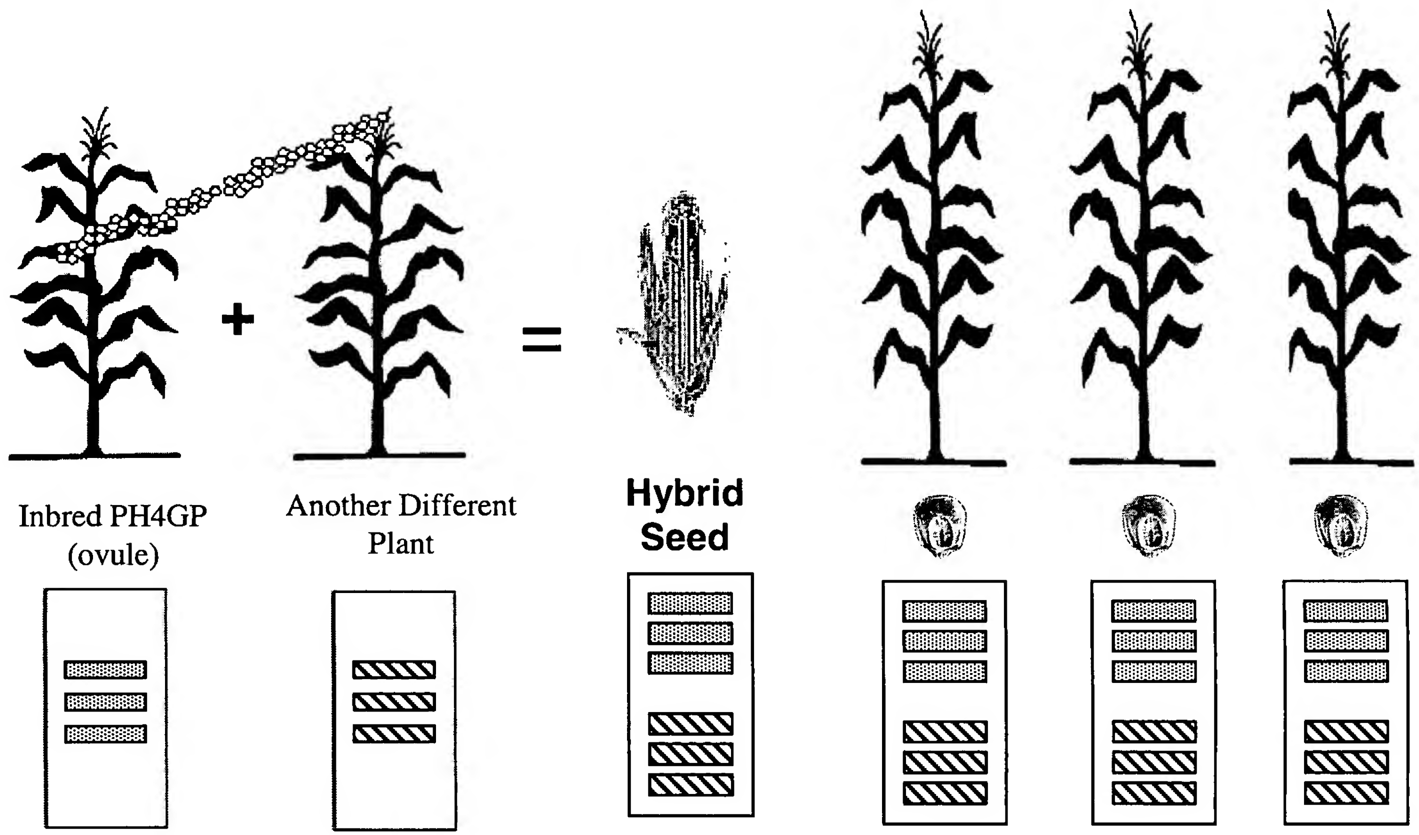

Exhibit 4: Wych (1988) Production of Hybrid Seed, Corn and Corn Improvement, Ch. 9, pp. 585-586

Included in the Information Disclosure Statement filed by Applicant in the present case. First cited by Applicant in March 11, 2003 Amendment, p. 14 in the parent application, 09/758,713, issued as U.S. Patent No. 6,720,487. The Examiner's May 23, 2003 Office Action was entered in response to the Amendment.

9 Production of Hybrid Seed Corn

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The objective of this chapter is to present a current, state-of-the-art description of seed corn (*Zea mays* L.) production as it is commercially practiced in the late 1980s. The chapter draws heavily on the treatment by Craig (1977), but will highlight changes in the industry and in technology since that chapter was written.

9-1 HISTORICAL PERSPECTIVE

The first commercial hybrids were produced and sold in the early 1920s. From that modest beginning our present-day sophisticated hybrid seed corn industry has developed. Crabb (1947) described the first production of hybrid seed corn in Iowa:

> "The first contract ever drawn for the production of seed for hybrid corn gave [George] Kurtzweil the exclusive right for all time to produce the Copper Cross hybrid, a contract which, although it hasn't been exercised for a good many years, is still one of Kurtzweil's most prized possessions."
>
> "[Henry A.] Wallace said he had foundation inbred material to plant a one-acre seed plot, and the decision was made to produce the first commercial hybrid seed corn ever grown in Iowa . . . Wallace turned the seed over to Kurtzweil [in 1923]. The old East Leaming inbred was used for the seed parent, and the meager supply of the Bloody Butcher line was used as the pollinator parent. Only by very sparse and careful planting was Kurtzweil able to plant the plot that measured almost one acre on a small farm owned by Kurtzweil's father, Mathias Kurtzweil, at Altoona, just east of Des Moines . . ."
>
> "The first detasseling of commercial hybrid seed corn in Iowa was done entirely by a woman, Ruth Kurtzweil, a sister of George . . . From the time the first tassels of the parent plants began to appear on the Leaming inbred, Miss Kurtzweil went up and down, pulling them out. Few fields of hybrid seed corn since have been detasseled with such care and interest. Now that producing hybrid seed corn has become such a tremendous enterprise, Miss Kurtzweil delights in calling her friends' attention to the fact that she once detasseled all the hybrid seed corn production fields in the State of Iowa."
>
> "Copper Cross earned another distinction in 1924 when it became the first hybrid developed in the corn belt to be purchased by farmers of Iowa and elsewhere. Approximately fifteen bushels—all that was available of Cop-

Corn and Corn Improvement—Agronomy Monograph no. 18, 3rd edition.

per Cross seed—was sold in the spring of 1924 at the price of $1.00 a pound, or at the rate of $56.00 a bushel."

The first hybrids to be developed were adapted primarily to the central Corn Belt; these were accepted slowly, and by 1933 approximately 1% of the Corn Belt corn acreage was planted with hybrid seed (Airy, 1955). Because of the superior performance of hybrids in the severe droughts of 1934 and 1936, farmers rapidly began accepting, and then demanding, hybrid seed.

The rapid acceptance by U.S. farmers of hybrid corn varieties in the 1930s and 1940s provided the basis on which many firms and individuals established themselves in a new and fast-growing industry. Prior to that time, only a few firms had been engaged in the hybrid seed corn business. Development of new hybrids adapted to virtually every corn-growing area of the USA and Canada helped to establish profitable corn production on hundreds of thousands of hectares outside the Corn Belt, where profitable corn production had previously been impossible on a commercial scale.

9–2 SIZE OF THE INDUSTRY

Since 1900, the area in the USA planted to corn has varied from a high of 47 million ha (116 million acres) in 1917 to a low of 24.4 million ha (60.2 million acres) in 1983 [the year of the federal government's payment-in-kind (PIK) program]. Excluding 1983, the area planted to corn between 1975 and 1985 averaged 33.4 million ha (82.5 million acres).

Planting rates vary considerably according to soil fertility levels, rainfall and irrigation availability, planting date, intended use (e.g., grain vs. silage), local custom, and finally, adaptation of specific hybrids to high plant populations. Assuming that a seed corn unit of 80 000 kernels will plant 1.4 ha (3.4 acres), it is estimated that a minimum of 24.5 million units of hybrid seed were required to plant the 1985 U.S. crop. At an estimated average retail price of $65/unit, the domestic hybrid seed corn industry has grown to a gross annual sales volume of $1.59 billion. Sales in other countries add to the total market.

9–3 TYPES OF HYBRIDS

The first hybrids produced and sold commercially were almost exclusively double crosses. However, several factors contributed to a significant transition from double crosses to single crosses within the U.S. Corn Belt, starting in the late 1950s and continuing through the 1980s. The transition to single crosses occurred because: (i) single crosses outyielded double crosses; (ii) a few companies led the way and others joined them to be competitive; (iii) farmers began to demand single crosses; and

(iv) improved agronomic practices and development by corn breeders of inbreds with higher per se yields made the production of seed of single crosses economically feasible. Single cross hybrids now comprise approximately 90% of the hybrid seed sold in North America (USA and Canada).

Modified single crosses, which are produced using related-line single crosses for either the female or male parent, were used extensively in hybrid seed corn production in the 1960s and early 1970s. Three-way crosses (single cross female parent and inbred male parent) are also a factor in the industry. Today, modified single crosses and three-way crosses account for about 10% of the North American market. While double-cross hybrids were once a significant factor in the market, their importance has decreased over the past two decades. It is estimated that they now comprise <1% of the total U.S. and Canadian market.

9–4 SEED CORN COMPANIES

Many firms have become involved in the production and sale of hybrid seed corn. Small, privately owned companies may produce and distribute only a few thousand units of seed. Operations of this size usually depend on inbred and hybrid development and research conducted by public institutions, or on that conducted by private firms that produce and sell parent seed (foundation seed) stocks. Smaller companies usually purchase foundation seed, produce their supplies of hybrid seed, and then sell it directly to farmers in their local areas.

Large companies usually carry on their own research and development programs, produce their own foundation seed stocks, produce the commercial seed, and distribute it through their own sales organizations. The majority of hybrid seed corn is sold by the various companies to farmer dealers, who, in turn, sell it to farmer customers. It is customary in the industry to deliver to dealers on a consignment basis, and to accept as "returns" seed that remains unsold by the dealer at the end of the planting season. Alternatively, the "sales agent" approach is used, with the seed remaining the property of the company until it is sold to the farmer customer (see section 9–12.2). In some geographical areas, sales are made by the seed company to jobbers or distributors who seek their own retail dealer outlets. This practice is more common in areas of relatively low sales volume.

Hybrid seed corn was at first sold in 25-kg (1-bu) packages. In the early 1960s, there began a trend to package and distribute in 23-kg (50-lb) packages. Later in that decade, the practice of packaging by kernel count became popular. At the present time, most seed corn is sold in units of 80 000 kernels.

The industry has seen both the attrition in the number of companies and great variation in the relative growth rates of individual companies. The many relatively small operations within the industry have a collective

market share of 36%, while the industry's seven largest companies have in total an estimated 64% share of the U.S. hybrid seed corn market (J. Ansorge, 1987, personal communication).

9–5 PRODUCTION OF PARENT SEED STOCKS

Large quantities of parent seed stocks (foundation seed) are required annually to plant the several hundred thousand hectares of commercial hybrid seed corn production. Most larger companies have parent seed or foundation seed departments responsible for the production and inventory of inbred and single cross parents needed for commercial seed production. In recent years, many seed companies have devoted increasing attention to developing more effective techniques and procedures to assure adequate supplies of high-quality, genetically pure stocks.

Seed corn companies must forecast future commercial seed sales and seed production plans to ensure availability of adequate parent seed supplies. Since most seed companies produce and sell many different hybrids, the number and supply of different parent seed strains that must be maintained for commercial seed production requirements is often quite large.

9–5.1 Foundation Seed Stock Increase

Foundation seed stock increase involves the maintenance and increase of inbred lines and single cross parent seed used to produce commercial hybrids. Inbreds are the basic foundation seed used in hybrid seed corn production. Inbreds must therefore be maintained and increased under rigid control to ensure satisfactory final product performance. Although procedures employed may vary among organizations, at least three important steps are usually taken: (i) establishing and maintaining a supply of breeder seed; (ii) increasing inbred seed; and (iii) producing related-line and/or unrelated-line single cross parent seed.

Breeder seed is usually derived from bulked, self-pollinated seed at the F_8 to F_{10} generation of inbreeding. The breeder has the responsibility of ensuring that the inbred is homozygous, uniform for plant type, and adequately represents the genetic constitution of the inbred. All inbred increases are made from this base population of breeder seed. Some companies have established separate programs to maintain supplies of breeder seed. Increases are produced in well-isolated blocks by natural random sib mating. In turn, this initial inbred increase is used to plant subsequent inbred seed increases and production of single-cross parents.

Both types of increase are made under stringent isolation. Procedures and standards developed by certification agencies (Hutchcroft, 1957; Cowan, 1972) indicate the importance of minimum isolation distances. Commercial companies certify all foundation seed that will be exported. Much of the parent seed for domestic use is not certified, but guidelines

developed over the years generally exceed, or at least equal, those of certification agencies.

Foundation seed fields are planned with isolation of 201 m (660 ft) as the base distance from other corn. Early studies by Jones and Brooks (1950, 1952) showed that: (i) the greatest contamination occurs in the 50 to 75 m (165–248 ft) nearest contaminating corn; (ii) pollen from border rows dilutes contamination; (iii) natural barriers may reduce contamination; (iv) an abundant supply of male corn pollen at the right time reduces contamination; (v) the direction of a field from contaminating pollen influences the amount of contamination; and (vi) "depth of field" in the direction of contamination source is important. Certification requirements in most states allow for substitution of additional male border rows for some portion of the 201-m isolation distance, but neither natural barriers nor time isolation are allowed to substitute for the required distances.

9–5.2 Procedures and Techniques

Generally, the equipment and procedures used in planting, detasseling, harvesting, drying, and conditioning of parent seed increases are similar to those used in commercial hybrid seed production. Some steps are applied more rigorously to ensure maximum genetic purity.

Variability among individual plants within the inbred population will sometimes occur. These off-types must be identified and removed (rogued) to avoid perpetuation of this variability from generation to generation. Careful plant removal (rogueing) must be practiced throughout the growing season to eliminate individual plants that exhibit phenotypes varying from the accepted phenotype of the inbred. As much rogueing as possible should occur prior to pollination to eliminate outcrossing resulting from pollen supplied by undesirable plants. Parent seed is usually harvested on the ear, allowing further selection (i.e., removal of off-type ears) to be practiced on the sorting table prior to drying and shelling (see section 9–9).

9–5.3 Quality Control

Rigid requirements must be used to maintain genetic purity at maximum levels. Genetic purity of parent seed not only helps ensure pure commercial hybrid seed but also reduces cost associated with rogueing commercial seed production fields and ear sorting at harvest. Parent seed is usually sized just as commercial seed corn. When genetic impurities occur, particularly those caused by outcrosses, they are often concentrated in specific kernel sizes, especially the large round kernels. As a result, certain kernel sizes within a specific lot may have unacceptably high levels of impurities, while other sizes in the same lot are acceptable. Careful selection of kernel sizes with the highest genetic purity can lead to improved purity of commercial seed corn.

Until relatively recently, the conventional approach to monitoring purity has been field "growouts". Growouts of a shelled corn composite of each seed lot from summer increase are often planted during the subsequent winter season to estimate genetic purity prior to use. In many cases more extensive growouts, sampling each kernel size in the lot, are conducted in the following summer growing season to obtain additional, more precise estimates of purity by kernel size. The accuracy of field growouts depends on: (i) securing a representative sample of the entire seed lot; (ii) a clean, uniform field to minimize volunteer corn and variation in plant height; (iii) favorable growing conditions; and (iv) knowledgeable personnel who are familiar with all the parental and hybrid plant phenotypes to score or "read" the growout.

Growouts are usually made in an area where the crop can be grown in the fall and winter months. Florida, Hawaii, Argentina, and Chile are most often used by U.S. seedsmen. Despite the use of winter growouts at these locations, it is difficult to obtain results early enough to make data-driven decisions on specific seed lots before the seed must be conditioned, bagged, and distributed. This is one of the factors that has led to increased reliance on electrophoresis results by some companies.

Starch gel electrophoresis (Cardy et al., 1980; Smith and Weissinger, 1984) is a recently developed technology that provides an additional means of purity analysis. The advantages of this technique include precision, rapidity relative to field growouts, absence of environmental influence on expression of genetically controlled characters, and the potential to make purity checks on developing embryonic samples collected prior to harvest (Smith and Wych, 1986). The disadvantages of this technique are the initial costs of the specialized equipment required and the cost of laboratory operation, or the relatively high cost per sample charged by commercial laboratories, if this alternative is chosen. Smith and Wych (1986) determined that the costs per seed lot for estimating percentage of female selfs by electrophoresis vs. growouts were approximately equivalent if both procedures were done in-house. However, if analysis for outcrosses is also conducted, the costs for electrophoresis may be somewhat higher than for estimation of selfs, only, due to the need to prepare and stain more gel slices. The urgency of the need for the purity information must be balanced against the comparative costs.

Seedsmen need to be aware that both growouts and electrophoresis provide useful information only to the extent that the samples are representative of a seed lot and adequate in size. The number and size of samples must be sufficient to provide an adequate measure of the variation within the seed lot being sampled.

Both growouts and electrophoresis can be used to identify accidental mechanical mixtures or mislabeling of foundation seed, which may occur at any point in production, conditioning, and inventory. For this application, electrophoresis has the same advantages and disadvantages mentioned above.

Another part of quality control of parent seed is germination. Various methods of measuring seed germination are employed and are generally performed on all usable kernel sizes of each seed lot. These methods are described in more detail later in the chapter (see section 9–11).

9–5.4 Storage and Inventory Control

Large inventories of parent seed are required. Accurate records of inventory supplies, genetic purity, and germination are maintained, since parent seed production is typically planned to provide an inventory adequate for 2 to 4 yr. Controlled environment storage facilities are used to maintain viability and quality (see section 9–12 for greater detail).

9–6 PRODUCTION OF COMMERCIAL HYBRID SEED

Agronomic practices in seed production fields are in general the same as those used to grow a commercial corn crop. However, there are some additional requirements unique to seed production. Acreages are determined on the basis of projected sales, utilizing yield levels based on breeders' research, production research, and past experience. The transition to the use of inbreds as female parents to produce single-cross hybrids has increased the need for planning, sound scientific and technical knowledge, and production technology to ensure economic success. Cultural practices used in production fields are planned to minimize risks while maximizing yield and seed quality.

9–6.1 Selection of Production Areas and Contract Growers

Successful commercial hybrid seed corn production begins with selection of a growing area and contract growers. Innovative farmers in cooperation with the seed companies have helped the seed corn industry grow into a sound business. Most seed corn production acreage is located in the Corn Belt. Expansion of the Corn Belt and increased technical knowledge have created opportunities for seed companies to expand in search of specific seed production areas. Production areas are chosen to provide such necessary factors as growing degree days, day length, lack of extreme temperatures, and specific farming practices, such as irrigation capability. By matching specific inbred needs to growing area characteristics, risk can be minimized and seed yields per female acre maximized.

Selecting growers within a production area is another important step. Generally, someone at the local production plant level will select growers who are among the most progressive and innovative corn growers in the area. The grower's location within the isolation block (see section 9–6.4) is also a factor. Seed companies attempt to select farms with high productivity indices and suitable soils that have been maintained in a state

of high fertility with good weed control. Tillage and cultural practices must be in line with approved hybrid corn production practices. Good soil structure and tilth are important in order to avoid the adverse effects of poor drainage and crusting on inbred stands. Since approximately 90 to 95% of the seed acreage will be devoted to inbred or related-line single cross parents, seed corn growers who will give special attention to management of insect and disease pests, weed competition, and fertility are needed.

Contract growers must be willing to cooperate with seed companies to alter their cultural practices and/or timing, rate, and kind of herbicides, insecticides, or fungicides. Equipment modifications are often necessary. In some areas, the seed company furnishes equipment on a lease or rental basis to the growers. In other cases, growers may cooperate in the purchase and sharing of various specialized pieces of equipment such as unit planters and detasseling and harvesting equipment.

9–6.2 Contracts

With the advent of single-cross hybrid seed production, contract growers were not content to assume the greater risks associated with inbred parents. As a result, base guarantees are made that involve payment, up to a predesignated yield level, for complete failure of the seed crop. Incentive payments are often based on published futures or cash market prices at a specified time and place. In some instances, contracts are based on government based yield calculations or locally measured commercial hybrid corn yield checks.

Usually, the type of contract used, base guarantees, and multiplier factors are based upon anticipated yield levels and degree of difficulty encountered in the production of each individual hybrid. Factors such as fertility, herbicide or insecticide costs, seedbed preparation for split-date plantings, volunteer removal, and harvesting are items for consideration within the contract. There are considerable variations in contracts among companies.

9–6.3 Management of the Production Area

The management staff at a production plant are responsible for all aspects of production. They are assisted by trained supervisory help, especially during planting, detasseling, and harvesting periods. An area of 4000 to 6000 ha (10 000–15 000 acres) of seed production responsibility is fairly typical for a production plant manager and his/her staff. Within this acreage, regional (or area) supervisors are charged with responsibility for 400 to 800 ha (1000–2000 acres). During detasseling, additional supervisory help may be employed as crew foremen, field foremen, and inspectors. The demand for additional supervisors during the summer months offers opportunities to utilize agriculture and science teachers,

principals, and other professionally trained personnel during their school vacation periods.

Communication is essential for production plant managers and area supervisors to be effective in the management of their respective areas and for coordination of activities. Particularly during detasseling, it is critical that communication be available so that people and equipment can be effectively used and moved to high priority areas as needed. Many seed companies use a combination of mobile telephones, Citizen's Band radios, and FM two-way radios.

9–6.4 Isolation of Seed Fields

Isolation is intended to assure that the hybrid cross is produced with a high degree of genetic purity. It has often been said by seedsmen that the best isolation is a perfect nick, that is, when a pollen parent starts shedding just before the female parent's silks start to emerge beyond the husk or tip of the ear shoot. In addition, plant management personnel must work with each individual contract grower to establish the location and boundaries of each seed field to conform with isolation distance requirements. Preference is also given to crop rotation of corn following soybean [*Glycine max* (L.) Merr.] (rather than following corn), because volunteer corn problems are avoided and seed corn yield is higher.

Minimum standards for isolation of seed corn production fields have been established (Anonymous, 1971) for the USA and Canada; nevertheless, some variation exists among states. When zero or one male border row is present, minimum distances ranging from 125 to 201 m (410–660 ft) are typically required between the female parent of the hybrid being produced and any other corn of the same seed color, maturity, or endosperm type. Isolation distance of 201 m is required where possible contaminant corn may have different kernel color or endosperm type. Additional distance is sometimes employed where contaminating corn may be of decidedly different pollen shedding ability (such as tropical hybrids), and where wind velocities may be high, such as in production areas near large bodies of water.

Minimum isolation distance requirements can be modified by: (i) additional border rows (Fig. 9–1); (ii) size of field and production block; and (iii) adequate natural barriers and differential flowering dates (in some states). Jones and Brooks (1952) found that natural barriers are not as effective as border rows of corn. Differential flowering times are effective in isolation if silks of female parents are not receptive when pollen from other than the male parent is present.

To optimize genetic purity, a timely nick between receptive silks on the female parent and pollen shed by the male parent is required. Differential planting dates of seed parents are often required to achieve this. Abundant amounts of male pollen are also beneficial, and some companies utilize high population density in the male parent rows to increase pollen load.

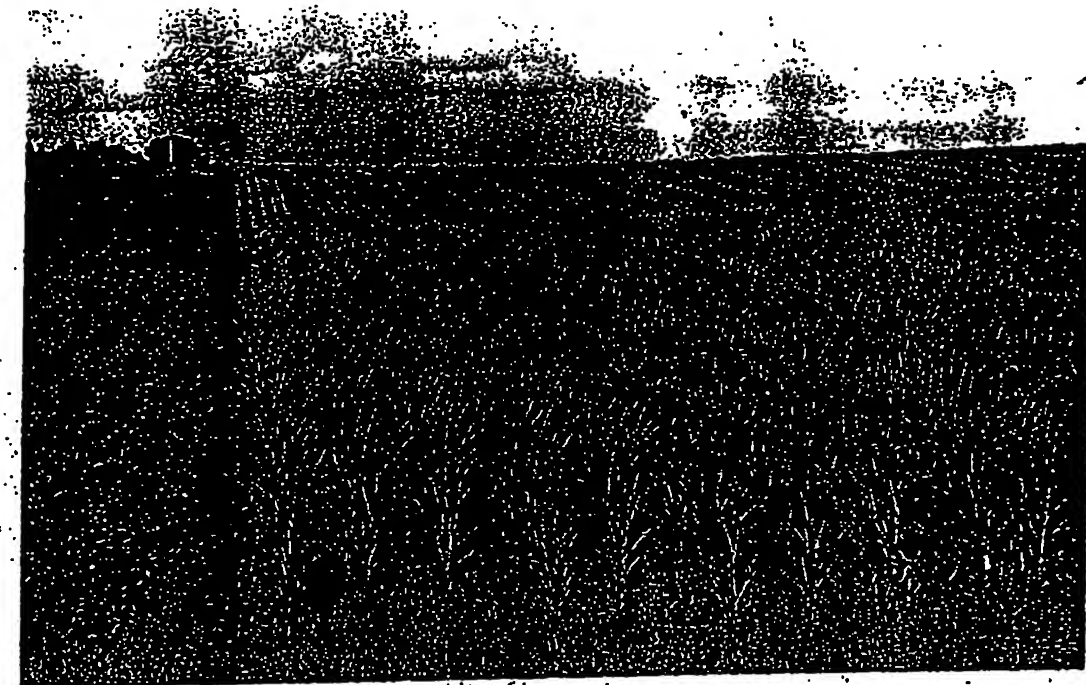

Fig. 9–1. A commercial hybrid seed production field showing additional male parent border rows for the purpose of providing pollen saturation adequate to ensure genetic purity of the hybrid seed. The strip of soybeans on the left provides the required isolation distance.

9–7 PLANTING THE SEED FIELD

9–7.1 Planting Date

The minimum soil temperature for growth of corn is generally regarded as 10 °C (50 °F). Most agronomists would also agree that the optimum time for planting corn is as soon as the soil temperature at the 5-cm depth reaches that temperature for a relatively sustained period of time. Soil moisture and potential for compaction must also be taken into account. Numerous studies indicating the advantages of early planting upon yield were reviewed by Craig (1977). More recent work is summarized by Hicks and Wright (1987) and Johnson and Mulvaney (1980).

9–7.2 Fertility

In general, inbreds have poorer rooting ability than hybrids, and may therefore be more vulnerable to nutrient deficiencies and imbalances. In the past, it has been the tendency of contract growers to overfertilize to protect against possible fertility deficiencies, while at the same time striving for a balanced fertility program. Decreases in commodity prices (upon which contract payments are based) and hence economic pressures on seed growers, as well as growing concern about groundwater contamination, suggest the need for a closer examination of fertilizer recommendations. Contract growers are encouraged to use soil tests regularly and to apply nutrients only as necessary to maintain fertility levels.

9–7.3 Herbicides, Insecticides, and Fungicides

Control of weeds, insects, and diseases within the seed field have become an integral and necessary part of seed production. Since inbreds and related-line parents are less competitive than hybrid corn with broadleaf weeds and grasses, seed growers rely heavily on herbicides for effective weed control. Production personnel work with the grower to develop a weed control program that takes into account specific weed problems, crop rotation, soil type and organic matter, equipment, and the specific parents involved with the hybrid to be produced.

Insecticides for the control of above and below ground insects are generally a must. Most companies have formulated programs that protect against insect damage to stands, the growing plant, and the female parent ear. In recent years, some seed companies have begun to rely heavily on IPM (integrated pest management) principles and scouting of seed fields to determine if and when insecticide application is justified. Selection of the insecticide to use will depend upon the specific insect to be controlled, efficacy of alternative insecticides, the level of infestation, the development stage of the seed crop, safety considerations, and the reentry period.

Fungicides have also become a regular part of the production program for protection of the more susceptible parent lines to damaging fungal diseases. Genetic resistance to disease is preferred, but chemical protection is often needed when resistance is not adequate in the parent line. Spray programs have been effective in reducing damage from foliar disease on the more susceptible lines. Monitoring the crop for disease development is beneficial in making timely applications of chemicals. Fungicides are widely used as seed treatments to give protection against seed and seedling diseases (Shurtleff, 1980).

9–7.4 Plant Density

Plant density within the seed field is planned to produce maximum yields of high purity seed of saleable kernel size. Upper limits may be imposed by the particular germ plasm being used, the average rainfall pattern or irrigation availability in the production area, and local labor supply for detasseling. Many investigators have studied plant density effects on yield of hybrid corn (Craig, 1977; Johnson and Mulvaney, 1980). Fewer published studies of inbred response to plant density are available. Some seed companies conduct plant density trials with the female parents they are using in seed production. They evaluate the yield and kernel sizeout responses of those inbreds to increasing plant density. Plant densities in current use in seed fields typically range from 54 000 to 64 000 plants per ha (22 000–26 000 plants per acre) for inbred female parents, and often exceed that level for male parents, especially with inbred males that shed a limited amount of pollen.

9–7.5 Planting Patterns

Common planting patterns in seed production fields today include 4:1 (fours rows of female parent to one row of male parent) (Fig. 9–2), 4:2, 4:1:4:2, 6:2, and solid female with interplanted male. In the first three patterns, the female parent is never more than two rows from the male parent. One-half of the female parent rows are adjacent to a male parent in the 4:1 and 4:2 patterns, and two-thirds of the female parent rows are adjacent to a male parent in the 4:1:2:1 pattern. These contrast with the formerly conventional 6:2 pattern that was commonly used for production of double-cross hybrids. The 6:2 pattern is still used to produce some single crosses, but its use is generally restricted to male parents that shed an abundant supply of pollen.

Occasionally solid planting of the female parent in 96.5 to 101.6 cm (38–40 in.) rows is utilized with either every other or every fourth between-row space being interplanted with the male parent. This accomplishes two purposes: (i) full utilization of land area for female parent production; and (ii) placement of the male parent closer to the female parent rows. In stress environments, interplanting may lead to yield and quality problems. Solid plantings are typically limited to female parents not so aggressive as to overshadow the male parent and thereby delay pollen shed, and to reasonably short male delays. Also, it is advisable to restrict this practice to male parents of sufficient stalk and root strength to avoid stalk and root lodging, which would make it difficult to detassel the female parent or remove the male parent as soon as pollination is complete.

It is a practice of many seed companies to destroy the male parent by cutting or running it down (if it is brittle enough to break) after pollination is complete. Competition with the developing female parent for nutrients or available soil moisture should, in theory, be minimized and increased kernel size and/or seed yield may result. Production research conducted by the author's company has shown mixed results on kernel size and yield responses. Characteristics of the female and male parents involved and soil moisture availability after pollination are important factors contributing to the response observed. Destroying the male parent at this stage prevents grain formation in the male rows and eliminates the risk of seed contamination at harvest.

9–7.6 Parent Delay Techniques

Shoultz (1985) summarized the results of a recent survey of the seed corn industry's use of various parent delay techniques. Split-date planting of parents, the planting of the female and male parents on different dates, is used so that the two parents "nick", or reach the flowering stage concurrently (Fig. 9–3). This has been and continues to be the most popular method of making large alterations in flowering date, so that parents of differing maturities are brought together for a timely nick.

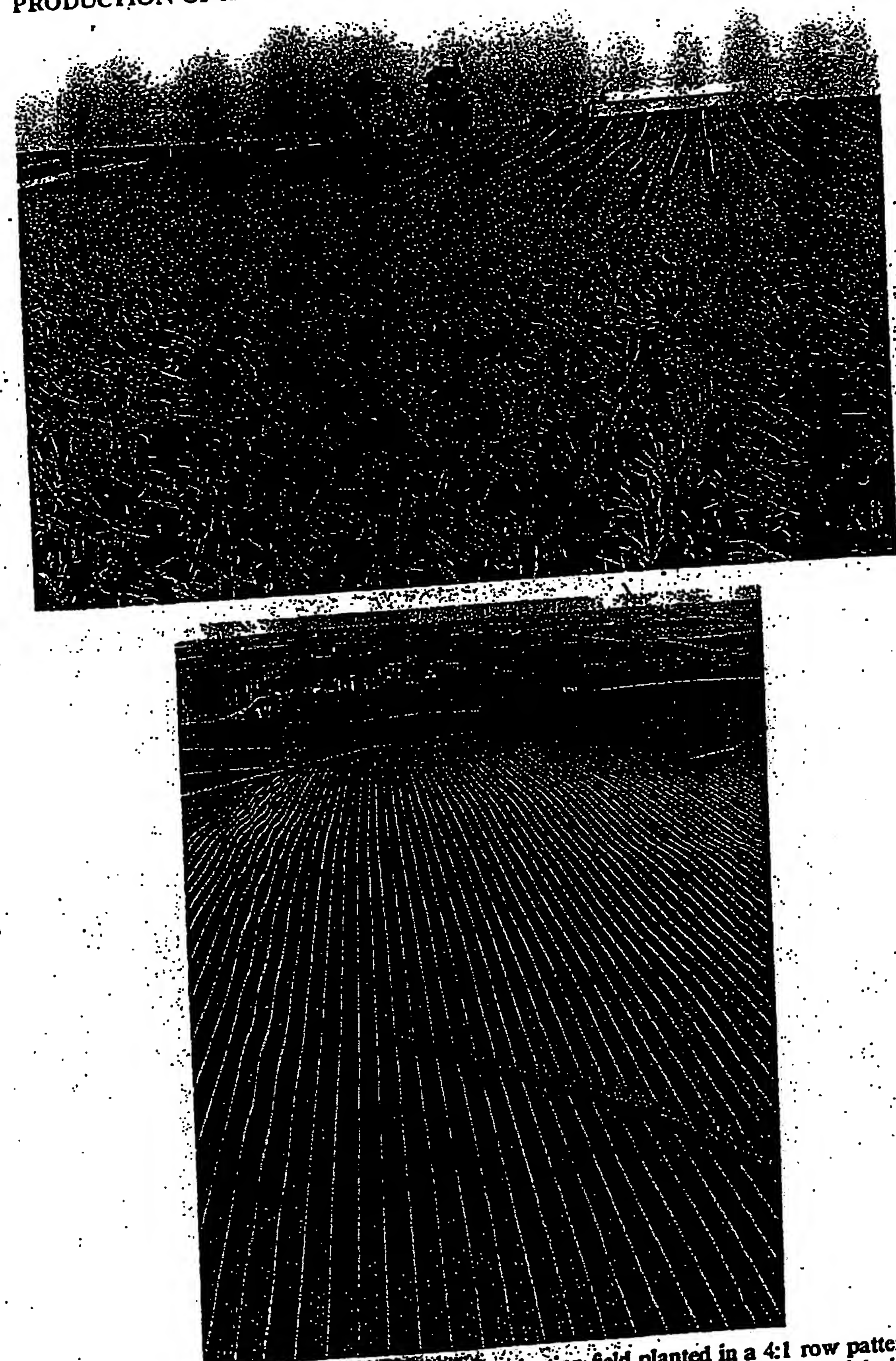

Fig. 9-2. (*Top*) A commercial hybrid seed production field planted in a 4:1 row pattern, with four detasseled rows (female) and one pollinator row (male). (*Bottom*) Aerial view of a commercial hybrid seed production field planted in a 4:1 row pattern, shown after detasseling. Note the border male rows on the left side of the field.

Fig. 9–3. Split-date planting of parents in a 6:2 row pattern. The female rows have emerged while the male rows are just being planted.

Split-date plantings are made on the basis of some combination of days, growth stages, and/or heat units accumulated from the time the first parent was planted (Shoultz, 1985). Most success has been realized by a combination of heat units and growth stage coupled with experience and good judgment. Male parents are often planted with a double delay to extend the pollen shedding period. Plantings are timed so that peak pollen shed coincides with maximum female parent silk exposure.

Other methods in common use for obtaining small adjustments to pollen shed are: (i) variable fertilizer rates; (ii) variable planting depths between parents; and iii) clipping (Cloninger et al., 1974) or flaming (Fowler, 1967) to retard development. These techniques can provide from 1 to 4 d delay in flowering, or extend the duration of flowering by as many as 2 to 4 d (Shoultz, 1985). Clipping and flaming are rarely used to delay the female parent because both techniques typically result in reduced seed yield. Clipping has been used effectively to save a crop when weather conditions have prevented planting the delayed parent when the early parent has already been planted. This has been particularly important when it is too risky to replant the early parent because too few heat units are left in the season or when a seed shortage exists for one or both parents.

9–8 POLLEN CONTROL

Pollen control refers to the practices employed to ensure hybridization by forced cross pollination between the female and male parents.

Pollen control in the hybrid seed corn production field is extremely critical. Various methods of pollen control in seed fields have been utilized or investigated. These were aimed primarily at reducing the cost or easing the difficulty at this critical time period, while still maintaining the desired genetic purity. The two most commonly used methods today are detasseling and cytoplasmic male sterility. Craig (1977) described two other methods, genic male sterility and chemical pollen control, which are not currently in widespread use.

9-8.1 Detasseling the Seed Field

Detasseling currently represents the most widely used method of pollen control. Detasseling involves the physical removal of the tassel from the female plant, either as a manual operation or in combination with mechanical devices. To ensure that each seed field meets the necessary quality (genetic purity) standards, tassels from the female parent rows must be removed before they shed pollen and/or before silks emerge on the ear shoots of the female parent. This is an expensive operation, currently costing the seed company from $250 to $320 per female hectare ($100 to $130 per female acre) for an average female parent. Increasing wage rates and deteriorating population demographics (labor supply and its distribution) are two factors that will continue to pose challenges to the industry.

Genetic purity of intended crosses is dependent on compliance with standards established by company management and certifying agencies (Anonymous, 1971). When the female parent has 5% receptive silks (silks emerged and turgid) the following standards, as established by certifying agencies, are employed: (i) the female parent is limited to 1% shedding tassels at any one inspection and to a total of 2% shedding tassels for three inspections at different dates; and (ii) off-types in the male not over 0.2% at any inspection. Some seed companies have established more rigorous standards; e.g., not over 0.5% female shedders allowed at any one inspection and not over 0.1% male off-types per inspection. Tassels are counted as shedding when more than 5 cm (2 in.) of the central spike and/or side branches have emerged and have shedding anthers.

Major seed corn companies hire and train seed field inspectors to observe pollen control operations, report irregularities, and assist in interpreting rules for the detasseling/rogueing supervisors. These inspectors may be assigned as many as 810 to 1620 gross ha (2000 to 4000 gross acres). Before detasseling begins, they establish compliance with isolation requirements and check for volunteer corn and/or off-type plants in both female and male parent rows. When detasseling starts, the inspectors check fields to be sure that female parent tassels and off-types in male rows are properly removed. The objective is to keep those who are responsible for achieving genetic purity (plant management, area foremen, and detasseling contractors) informed, and to prevent any violation of

standards. If isolation, detasseling, or rogue removal standards are not met, inspectors report the details to plant management, so that a decision regarding corrective measures can be made.

9-8.2 Manual or Hand Detasseling

Each year thousands of workers, usually teenage youth, are employed by seed companies to perform the hand detasseling operation. This activity may last only 1 week, but may continue up to 5 weeks or more depending upon the volume of production and spread in female parent maturities planted within a seed production area. Several factors influence the magnitude and complexity of this job:

1. Tassels must be removed from all female plants in a timely manner, as previously discussed.
2. When weather conditions favor rapid corn growth, fields must be covered daily; this requires 7-d workweeks, rain or shine.
3. Some female parent plant types are easier to detassel than others.
4. Female parents whose tassels begin shedding pollen before fully emerging from the upper leaves, or which silk at about the same time as pollen shed occurs, create difficult detasseling supervision, management, and purity problems.
5. Weather conditions can greatly aid or complicate the detasseling season. A heavy rain or windstorm can lodge and tangle the female parent just as tassels emerge, making walking or driving through the field more difficult. Extreme heat can affect both the efficiency of detasselers and the emergence of silks and tassels.

Detasselers are usually organized into crews ranging from 6 up to 40 or 50 workers. The crew supervisor is responsible for recruiting, transporting, training, managing, and controlling the detasselers in his crew. With larger crews, the supervisor will have one or more assistants (sometimes called checkers) to help in crew training and managing the job to be done in the field. There will customarily be one supervisor or checker for each 6 to 10 crew members. It is important that each crew member be trained in proper detasseling technique, to minimize leaf damage and to ensure an effective detasseling job in each female parent row. The crew supervisor is also responsible for the safety and comfort of the workers while in the field.

For more effective and efficient labor utilization, detasseling carts or personnel carriers (Fig. 9-4) are frequently used, especially for detasseling taller-growing inbreds or single-cross female parents. These carts are motorized high-clearance machines equipped with platforms upon which the workers stand as they remove the tassels. The machines move slowly through the field, enabling the detasselers to look down into the plant canopy and remove the tassels more effectively and easily than if they were on foot. Usually 12 detasselers will work from each machine; for maximum effectiveness it is therefore important that all detasselers on

Fig. 9-4. A high clearance personnel carrier transporting detasselers through a seed production field. This view depicts the "second pass" through this field; during this trip, late-emerging tassels are removed.

each machine be equally skilled. It is often difficult or impossible to use these machines immediately after heavy rain or windstorms, and the detasselers must then proceed on foot.

Some seed companies employ contract detasselers for at least a part of their seed production. With this method, the contractors agree to detassel specified field areas for an established fee paid to them by the seed company. The contractors may work their own hours as long as they meet the company's established standards for timely removal of tassels. If they fail to do so, the seed company reserves the right to bring in a crew or mechanical detasselers to remove the potential problem-causing tassels before they shed pollen, and to deduct this expense from the contractor's payment. Contractors typically provide transportation for themselves and any other detasselers they employ, as well as the necessary supervision. This method often permits people employed in other jobs to earn extra income during their free time.

9-8.3 Mechanical Detasseling

Craig (1977) summarized several factors that led to increased use of mechanical detasselers in the early 1970s. Availability and cost of labor for manual detasseling continue to concern seed companies, and work to improve equipment for mechanical detasseling is ongoing.

Mechanical detasselers (Fig. 9-5) are self-propelled, high-clearance machines capable of operating even in extremely muddy fields. They fall into two basic types:

1. Cutters—a rotating cutter blade or knife cuts or shreds the top of

Fig. 9-5. (*Top*) A "wheel puller" machine used for mechanical detasseling of the female rows in a seed production field. (*Bottom*) Close-up view of the wheels in action.

the corn plant, including the tassel; the blades operate at various planes, from horizontal to vertical, and are adjustable in height.

2. Pullers—usually two counter-rotating wheels or rollers, adjustable in height, grasp the tassel and upper leaves and pull them upward in a manner approximating a hand detasseling operation.

The efficiency of mechanical detasselers is affected by many variables in the seed field, such as female parent morphology (leaf and tassel orientation), uniformity of female parent plant height and development, and skill of the operator. Mechanical detasseling produces best results when it is done in a uniform seed field in which the tassel is well exserted ahead of pollen shedding. As conditions become less favorable, percentage of tassels removed per pass will decrease and leaf damage will increase. The typical objective in the use of mechanical detasselers is to delay the operation as long as possible before silk emergence, to permit maximum exsertion of tassels, enabling their removal with minimum leaf damage. However, this delay increases the risk of leaving "sprigs" (partial tassels) or "hangers" in the leaf canopy. Hangers, as tassels that become lodged in the leaf canopy are sometimes called, are capable of shedding pollen for 2 to 3 d after removal (D. Langer and P. Downes, 1982, unpublished data). Hangers can lead to increased levels of female selfs, and are one of the chief objections that some companies have to mechanical detasseling machines. In all cases, some hand labor is required to move hangers to the ground and to pull entire tassels or sprigs remaining on missed, late, or short plants, or on tillers.

With most female parents, the combination of mechanical and hand detasseling will result in a cost savings when compared with hand detasseling alone. Current detasseling costs range from \$198 to \$247 per ha (\$80–\$100 per female acre) with a combination of mechanical and hand detasseling, compared to \$296 to \$321 per ha (\$120 to \$130 per female acre) for all hand detasseling (W. Beck, 1987, personal communication).

Cost savings attained through mechanical detasseling may be offset by seed yield reductions if the operation is not carefully managed to minimize leaf damage (Craig, 1977, unpublished data). To decide whether or not to use mechanical detasseling, seed companies and plant management consider variable production costs, especially current detasseling wages, and available labor supply, and weigh them against characteristics of the female parents involved and the size of the detasseling operation they face.

9–8.4 Effect of Detasseling on Seed Yield

The resumption in 1971 of detasseling as the primary method for pollen control (see section 9–8.5) renewed interest in the effect of detasseling on yield. The effect of detasseling on seed yield was considered more critical then, since inbred females had become involved due to the transitional adoption of single-cross hybrids. The development of various

types of mechanical detasseling machines also added a new dimension. A discussion of the effect of detasseling and leaf removal on seed yields of the female parents of double-cross hybrids may be found in Craig (1977).

Published work on leaf removal with inbred lines indicates that the yield response is generally similar to that of single crosses. In theory, removal of only the tassel could result in a yield increase, due to decreased shading of upper leaves and reduced competition for photosynthate and nutrients between the ear and the tassel. Hunter et al. (1973) removed the tassel, only, from 10 inbreds and observed an average increase in yield of 6.9%. As more leaves were removed with the tassel, however, greater yield reductions typically occurred. When one, two, and three leaves were removed with the tassel, yield reductions averaged 1.5, 4.9, and 13.5% relative to the yield where the tassel alone was removed. Cantrell and Geadelmann (1981) removed the tassel with two leaves. They observed yield reductions ranging from 9 to 13% across four early maturity inbreds, with an average of 11.6% yield reduction. Several other workers have reported differences among inbreds in sensitivity to yield reduction following varying amounts of defoliation (Cantrell and Geadelmann, 1981; Hunter et al., 1973; Vasilas and Seif, 1985b).

It is common to observe greater yield reductions after mechanical detasseling than after hand detasseling. Studies conducted by seed companies with mechanical detasseling machines have shown varying results. Craig (1977) cited unpublished research in which the yield of mechanically detasseled plots was from 2 to 40% less than that of hand detasseled treatments, depending upon the inbred involved and the number of mechanical cuttings. Unpublished research by C. Carter and R. York (1979, unpublished data) compared hand detasseling with wheel pullers on inbred females. These workers observed yield reductions ranging from 2 to 46% depending on the inbred line, number of wheel pulls, and timing of the wheel pulling operation.

Measurements have been made on the yield components affected by detasseling, to determine which are primarily responsible for reduced yield (Hunter et al., 1973; Pucaric and Gotlin, 1979; Vasilas and Seif, 1985a; Craig, 1977). The variables involved in these studies included the following: (i) the time of cutting or tassel removal in relation to plant development; (ii) the climatic conditions prior to, during, and after tassel removal; (iii) morphological differences among genotypes; (iv) type of detasseling machine; (v) the number of times cut or pulled; and (vi) the skill and attention of the machine operator. Although kernel number has most often been the major contributing factor, results have varied due to the differences in severity and timing of treatments employed. These complexities mean that precise statements regarding the effect of detasseling treatments on yield components cannot be made.

9–8.5 Cytoplasmic Male Sterility

For about two decades prior to the epidemic of southern corn leaf blight that swept the USA in 1970, the conversion of inbred parents to Texas cytoplasmic male sterility (*cms*-T) replaced detasseling as the predominant form of pollen control (Craig, 1977; Ullstrup, 1972). Though other male sterile cytoplasms were available, the T source (Rogers and Edwardson, 1952) proved to be the most satisfactory, because more inbreds were completely sterilized by T cytoplasm and genetic fertility restoration was more easily accomplished in this cytoplasm.

After the 1970 epidemic, the realization that the nearly complete conversion to T cytoplasm increased the vulnerability of the corn crop (NAS, 1972; Ullstrup, 1972) prompted a retreat from the extensive use of cms as a substitute for detasseling. In addition to T cytoplasm, many other male-sterile cytoplasms had been identified (Beckett, 1971; Duvick, 1965); of these, the C and S cytoplasms were the best known (Duvick, 1972). Since the use of cms was still a cost-competitive and satisfactory technique for hybrid seed production, C and S cytoplasms became important again in the late 1970s and early 1980s.

The American Seed Trade Association (ASTA) recently conducted a survey of the type of cytoplasm used in the production of seed corn to be sold in the USA. Based on number of units of expected sales for 1987, 66.1% of the seed corn was produced using 100% normal (N) cytoplasm, 22.1% involved production with *cms*-C cytoplasm (1.9% involving 100% *cms*-C and restorers, and 20.2% involving blends with N cytoplasm), and 11.5% involved *cms*-S cytoplasm (0.4% using *cms*-S and restorers, and 11.1% involving blends with N cytoplasm) (W. T. Schapaugh, 1987, letter to member companies responding to ASTA Corn Cytoplasm Survey).

There are two major ways in which cms has been used to facilitate the crossing of two inbreds. In the first case, detasseling is eliminated through the use of a female parent for which the cms conversion is completely male sterile. No detasseling is required. The other case involves combination of C or S cytoplasms in certain genetic backgrounds that result in only partial male sterility. In this situation, anther exsertion is delayed 1 to 10 d (Duvick, 1965) and usually commences after the tassel is fully extended above the leaves. At this point, mechanical detasseling can be accomplished with minimum leaf removal.

Consider the production of the single cross, A × B. If inbred A is nonrestorer genotype (rf/rf) that has been put into a male sterile cytoplasm by backcrossing, one can plant blocks of cms female A alternating with blocks of inbred B (the male) and produce completely cross-pollinated seed on inbred A without detasseling. If inbred B is also a nonrestorer genotype, the hybrid plants in a field of commercial corn would also be pollen sterile; if inbred B carries dominant restorer genes (Rf/Rf), however, the hybrid (Rf/rf) will shed pollen.

Since restored hybrids do not always shed adequate pollen (Duvick,

1959), the use of the restorer system introduces some risk for both the farmer and the seed company. Consequently, most single cross production is likely to involve a nonrestored genotype, in which from 25 to 50% of fertile hybrid seed, produced by detasseling, is blended with 50 to 75% of seed of the same hybrid produced by the cms method. This blending results in 25 to 50% of the hybrid plants in the farmer's field that will shed pollen normally.

Various methods of blending to assure complete mixing are practiced. One method is to flank the pollinator with alternating blocks of cms and normal (fertile) cytoplasm female. Another method increases the scale by planting alternating quarters of the field in sterile or normal female. Harvesting entails making one trip across the field in the cms female and a return trip through the normal female. By the time the ear corn reaches the conditioning plant, the ears of the two cytoplasms are thoroughly mixed.

9–8.6 Other Types of Sterility

Craig (1977) described in some detail the "Patterson method", which employs genic male sterility in the production of hybrid seed corn. This method is not widely used today, however, since the conversion of inbreds is complicated, time consuming, and expensive. Furthermore, additional expenses, in the form of foundation seed production inventory and quality control, are required.

Use of chemically induced male sterility in commercial hybrid seed corn production is an idea that has received considerable attention (Craig, 1977). Despite substantial research and development effort by several agricultural chemical companies, there is essentially no recent published work on this subject for corn. Likewise, a dependable and affordable commercial application of chemical hybridizing agents for seed corn production has not yet been discovered and/or developed (S. L. Kaplan, 1987, personal communication). To date, the major stumbling blocks have been either insufficient sterility percentage (Bollinger et al., 1978) or associated female barrenness (A. J. Cavalieri, 1987, personal communication).

9–9 HARVESTING THE SEED CROP

Harvest of the hybrid seed corn crop is, by necessity, closely coordinated with the operations of conditioning facilities at the production plant. The following discussion describes the operations generally used at a typical large production plant (Fig. 9–6). There are variations among companies and among locations within a single company. All operations from husking to distribution may be done at one location. Alternatively, harvesting, sorting, drying, and shelling may be accomplished at a plant

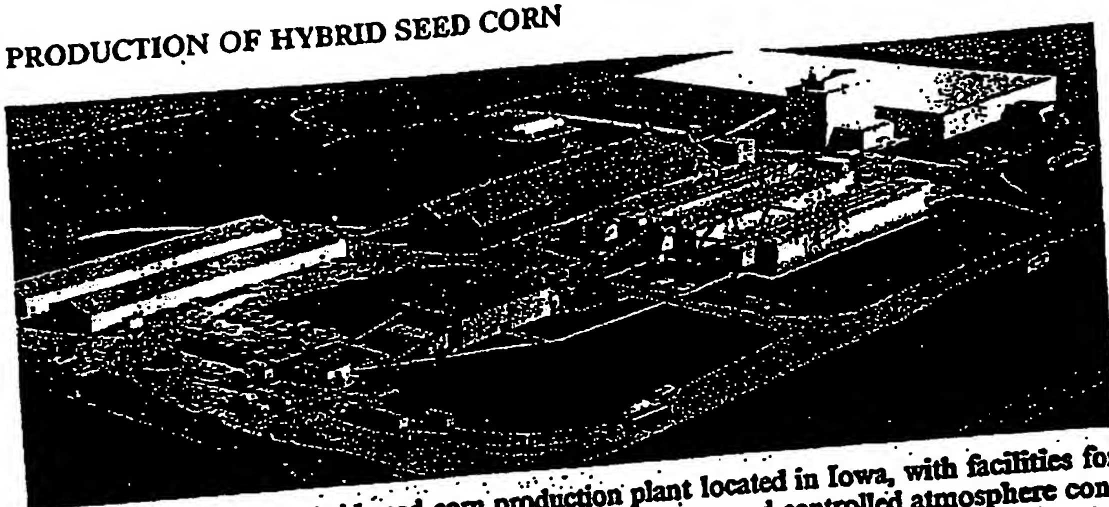

Fig. 9–6. A modern hybrid seed corn production plant located in Iowa, with facilities for all steps in conditioning, bagged seed storage in year-round controlled atmosphere conditions, and distribution of seed.

near the growing location, while the sizing, cleaning, bagging, storage, and distribution are done at other more centralized locations.

9–9.1 Maturity and Seed Quality

Harvest of the seed crop usually begins just before the developing kernels approach physiological maturity, the stage at which the kernels have reached their maximum dry matter accumulation. The moisture percentage at which kernels of inbred corn reach physiological maturity varies with genotype and environment, and ranges from 30 to 38% (A. J. Cavalieri, 1987, unpublished data; Knittle and Burris, 1976). Generally, harvest will begin when the moisture level of the seed is between 30 and 38%. The target moisture level depends upon factors such as the female parent, environment, weather forecasts, production volume and, finally, production plant capacity.

For planning purposes, projected harvest dates are typically estimated by monitoring kernel moisture percentage and heat unit (or growing degree day) accumulation, in combination with "black layer" formation (Daynard, 1969, 1972; Daynard and Duncan, 1969) and/or progression of the "milk line" (Afuakwa and Crookston, 1984). Genetic variation for field drying rates has been observed among inbreds (Carter and Poneleit, 1973; A. J. Cavalieri, 1986, unpublished data), and may be taken into account.

Timely harvest of the seed crop provides the seed company several advantages, including minimization of: (i) risk of freeze injury; (ii) field losses from mechanical pickers; (iii) risk of harvest delays due to adverse weather conditions; and (iv) quality deterioration due to insect damage, ear molds, stalk rots, and other diseases. Each of these factors contributes to the quality of the seed crop by reduction of physical damage, preservation of physiological vigor, and enhancement of appearance.

The adverse effect of freeze damage upon seed germination is a major risk to seed corn companies (Airy, 1955; Burris and Knittle, 1985). Ross-

man (1949) concluded that the amount of damage by freezing depended on temperature, duration of exposure, moisture of seed, genotype, husk protection, stage of development, and rate of drying after freezing. Studies reported by Neal (1961) indicated that injury to germination from freeze damage is directly related to kernel moisture as well as intensity and duration of exposure. The higher the moisture, the greater the effect on germination at all levels of freeze treatments.

9–9.2 Field Operations

The contract grower is responsible for harvesting the seed crop and delivering it to the production plant. Most mechanical harvesters used today are self-propelled ear corn pickers with three, four, or six-row heads (Fig. 9–7). Reduction in mechanical damage from the harvesters is accomplished by removing pegs from the husking rolls and properly adjusting the husking beds. Since harvest rate is ultimately determined by dryer capacity, a well-coordinated schedule directed by the production plant management is necessary to keep field harvest operations moving smoothly and dryers at full capacity.

9–9.3 Plant Operations

The seed is weighed as it is delivered to the plant. As the load is being dumped for movement into the husking/sorting building, the ear corn is sampled to accurately represent the grower's production of each hybrid. If maturity or moisture varies within a grower's fields, more than one sample is secured. These samples are used for measurement of grain moisture percentage and the cob and husk percentage. These data are used to calculate weight of No. 2 shelled corn delivered, which is the basis of payment to the contract grower.

While final husking is still done in the field by some companies, more than 90% of the seed corn produced in the USA is transported to the plant before it is husked a final time, sorted, and then moved to the dryers (Stanfield, 1986). In a typical husking/sorting building, ear corn is conveyed from the green corn receiving area (Fig. 9–8) to storage bins above the husking bed. The action of the husking bed removes the majority of the remaining husks before the ear corn passes over the sorting table (Fig. 9–9). In some operations, a return conveyor takes unhusked ears back over the husking bed. Usually, from four to six workers per table sort the ear corn as it passes over the table. These workers remove any diseased, off-type, or off-color ears from the seed. After sorting, the seed is conveyed to the dryers.

9–10 SEED CORN CONDITIONING

Conditioning of seed corn is the series of activities that begins with drying the ear corn and ends with the seed being bagged. The primary

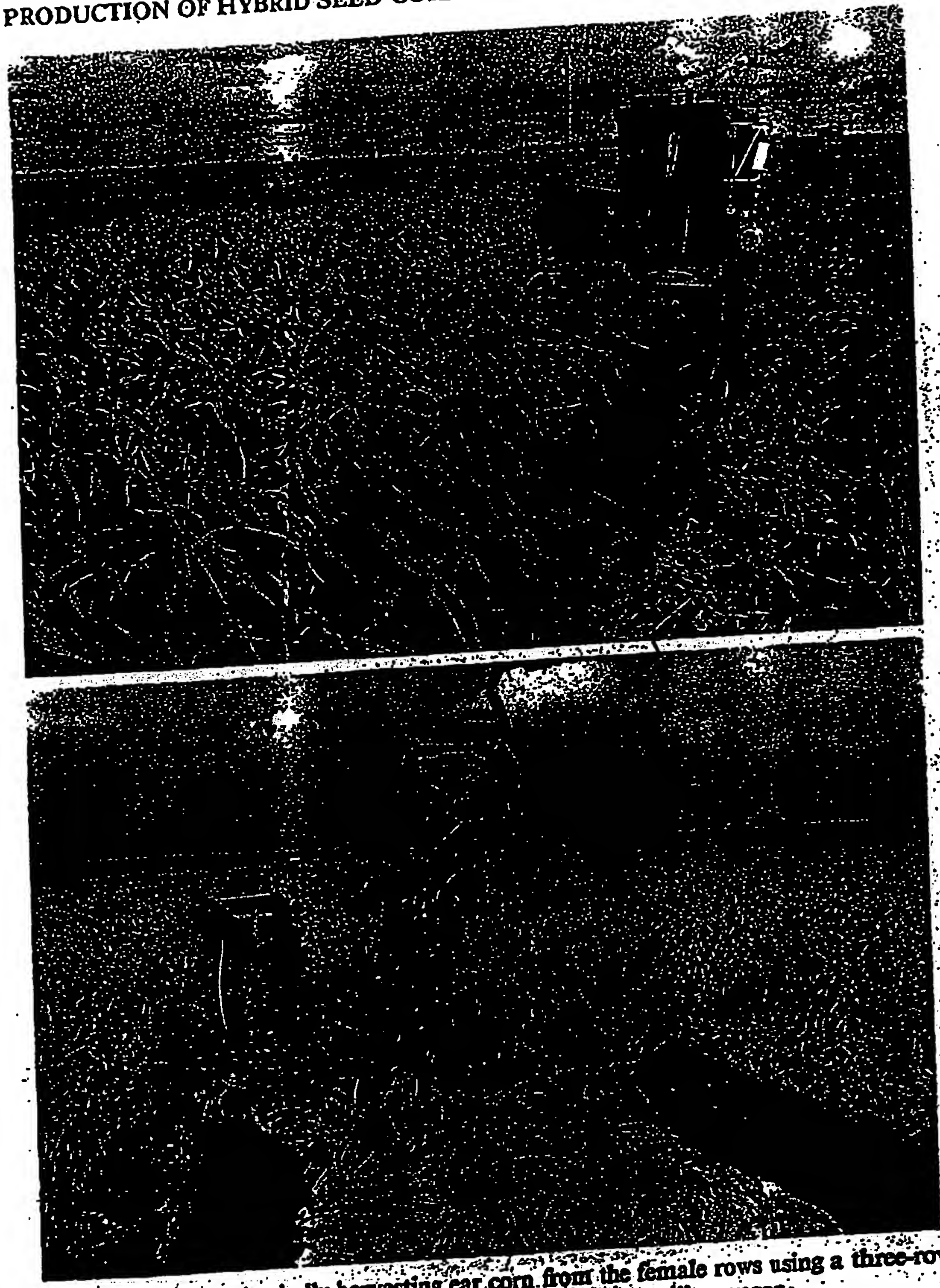

Fig. 9–7. (*Top*) Mechanically harvesting ear corn from the female rows using a three-row ear corn picker. (*Bottom*) The ear corn is elevated into a trailing wagon.

steps involved are drying, shelling, cleaning, sizing, treating, and bagging. These activities are accomplished in plants of all sizes and descriptions (Fig. 9–6). Although varying in engineering, all conditioning plants are designed and built to efficiently handle quantities of seed ranging from a few thousand to several million kilograms per year.

Certain objectives must constantly be addressed during the various

Fig. 9-8. Unloading seed corn at the green corn receiving area at a production plant. The ear corn is conveyed from this area to the husking and sorting building.

Fig. 9-9. The sorting operation in progress. Workers remove undesirable ears before the ear corn is conveyed to the dryer. The conveyer above the sorting table returns unhusked ears to the husking bed.

procedures of conditioning. First, the seed must be handled in a manner that minimizes mechanical damage. Any breaks that occur in the seed coat have a direct and detrimental effect on germinability and vigor of the seedling plant (Knake et al., 1986). The extent to which germinability

and/or vigor are reduced depends on both the severity and location of the mechanical damage (Wortman and Rinke, 1951; Wright, 1948). The effects of seed coat damage can be only partially offset by the application of fungicidal seed treatment (Knake et al., 1986; Tatum and Zuber, 1943).

A second objective of conditioning is to achieve maximum plantability within the limitations imposed by the sizing equipment. The objectives of sizing seed are to achieve uniformity of appearance and to maximize uniformity of kernel size and/or shape so that seeds drop accurately with either plate-type or plateless planters. The contemporary corn farmer, who is optimizing soil fertility, selecting hybrids best adapted to specific population densities, and planting for most efficient production, cannot tolerate significant fluctuations in stand.

Finally, the production plant manager must carefully maintain conditioning schedules to ensure the orderly movement of seed lots through distribution channels to meet delivery and planting schedules.

9–10.1 Drying the Seed

Seed corn dryers (Fig. 9–10) vary considerably throughout the industry. The majority of the systems utilize a squirrel-cage or axial-vane fan system to draw fresh air through a burner and force the heated air through bins filled with ear corn. Most burners today are fired with natural, butane, or propane gas.

Drying temperatures vary from 35 to 46 °C (95–115 °F). The entire

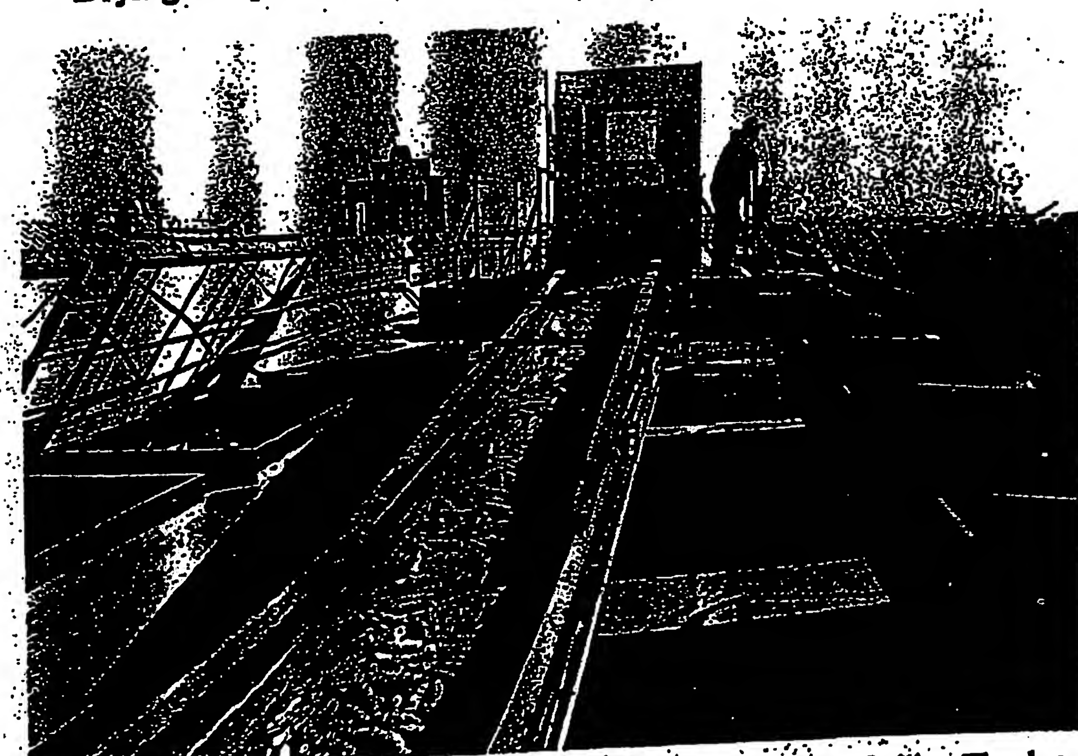

Fig. 9–10. Top view of an ear corn dryer at a seed corn conditioning facility. The doors are opened during bin filling, closed during the first half of the drying cycle, and then opened again to exhaust moisture-laden air during the last half of the drying cycle.

drying procedure is closely monitored since higher temperatures are detrimental to seed quality. Temperatures in the dryer building are measured at the point of contact with the seed. Temperatures above 45 °C (113 °F) have been reported as injurious to seed viability (Navratil and Burris, 1984; Craig, 1977), and high moisture seed is best dried at temperatures of 35 to 40 °C (95–105 °F) (Navratil and Burris, 1984; R. F. Baker, N. M. Frey, and R. D. Wych, unpublished data). It is also known that the higher the initial moisture content, the more susceptible the seed is to germination damage, and that genotypes vary in dryer sensitivity. Air temperatures of 46 °C (115 °F) may be used after moisture content of the seed has decreased to 20% or less, to complete the drying with minimal risk of germination injury. The seed corn is dried to 12 to 13% moisture, at which time it is conveyed to the sheller.

The moisture level to which seed corn is dried and held in storage also is critical. Cal and Obendorf (1972) showed that imbibition of low moisture (6%) corn kernels at temperatures of 5 °C (41 °F) resulted in malformed and delayed seedling growth. Sensitivity to imbibitional chilling was reduced when the initial kernel moisture was 13 or 16%.

9–10.2 Shelling the Seed

Shellers used for seed corn are designed so that when operated at low speeds, the seed is more or less rubbed from the cob. As the sheller speed increases, the action becomes increasingly pounding, kernel damage drastically increases, and germination declines (Airy, 1955). Therefore, it is desirable that all contact edges of the moving sheller parts be well smoothed to reduce damage. Experience has shown that with adequate horsepower, shellers can be operated at lower speeds and kernel damage is reduced by keeping the sheller full at all times.

9–10.3 Conveying the Seed

Since prevention of kernel damage is one objective of conditioning seed, it follows that each step should be evaluated to determine the amount of damage chargeable to that procedure. When studies such as this were done, some of the conveying equipment formerly used was found to be directly responsible for much of the mechanical damage (Craig, 1977). Grain augers crack and scuff seed; chain conveyors crush and crack kernels; and single tube elevator legs allow seed to be caught under belts and behind cups. Perhaps the greatest single source of damage is the dropping of seed from elevated conveyors into steel bottom bins or onto concrete floors.

Today, elevator legs are the double tube type and are equipped with either all plastic or plastic-lipped buckets. Chain conveyors are seldom used anymore, and augers have been replaced by belted conveyors. Breakage from impact on bin bottoms has been nearly eliminated by using grain spirals or ladders (Fig. 9–11) to lower seed gently with minimal

Fig. 9–11. Bulk seed in storage awaiting further conditioning and bagging. The spiral chute permits filling the bin while subjecting the seed to minimal mechanical injury.

impact. Whenever the fall distances are greater than 2 to 3 m, such equipment should be considered. Lateral conveying of seed is done either on rubber belting or with vibrating trough conveyors.

9–10.4 Cleaning the Seed

Seed corn from the sheller contains varying amounts of foreign material, consisting of bits of cob, husk, silk, pieces of kernels and, on occasion, insect larvae brought in from the field with the ear corn. Storage properties, plantability, and appearance of seed are greatly enhanced by removal of such debris. If not removed, the debris encourages storage insect problems and the development of hot spots when seed is stored for long periods. Aeration and cooling are improved by removing such foreign material, and less storage space is required.

Two types of machines are used in the first steps of cleaning seed, air screen machines and scalperators. With air screen machines, shelled corn is delivered to sloping shaker screens that remove wide, extra large kernels and cob pieces (over a 24/64; see section 9–10.5 for a description of screen size nomenclature) and narrow tip kernels (through a 15/64 or a 16/64). The seed then passes through a blast of air that lifts fines, small cob pieces, and dust which have escaped the screening action. With scalperators, shelled corn is fed onto a rotating wire mesh reel. Kernels and small cob fragments pass through the mesh, thus separating them from the larger cob pieces. An air chamber is then utilized to separate fines,

which are routed to a dust collector. Any grain removed is disposed of as feed or market corn.

When necessary, insects are controlled with an application of a slurry formulation of an appropriate insecticide to the shelled corn stream being conveyed into bulk storage bins. This is especially critical when there may be a delay between shelling and movement of bagged seed to cold storage following sizing, treating, and bagging.

In many operations, the shelled corn is cleaned again as the first step in the sizing towers. The air screen machines or scalperators (with a smaller mesh) are fed at a slower rate to achieve more extensive removal of fines and foreign material. A thorough cleaning prior to sizing is essential to: (i) reduce the amount of dust; (ii) ensure smooth rapid flow through the sizers; and (iii) permit cleaners (aspirators or gravity separators) at the end of the sizing system to operate more efficiently.

9–10.5 Sizing the Seed

9–10.5.1 Sizing

Sizing as used in the seed industry means separating kernels into uniform lots of sizes based on width, thickness, and length. The historic term *grading* carries a connotation of quality measurement that does not apply to the procedure. To determine screens to use in sizing, some seed companies secure a 760 to 1270 kg (30–50 bu) composite sample for each lot. These are run through a sample sizer to determine percent by size, kernel counts, plantability, and germination.

During sizing, seeds are passed through round hole cylinders in a descending series of screen sizes, which are measured in 1/128th in. (commonly referenced as one-half 64th of an inch). Screens are selected to separate the seed into large, medium, and small kernel sizes, and "tips" (narrow seeds for discard). In some systems, a divider cylinder is used to split the seed into "overs" and "throughs". The overs are separated with a larger screen into large and medium portions. A smaller screen divides the throughs into medium (combined with medium from the other separation) and small kernels. Another smaller round hole screen then removes the tips. Following this, slot screens from 12/64 to 14/64 are used to separate large kernels into large flat (LF) and large round (LR), medium kernels into MF and MR, and small kernels into SF and SR. Figure 9–12 illustrates this sequence. In contrast, some systems separate rounds and flats with slotted screens first. Then the rounds and flats are divided by round hole cylinders into large, medium, and small sizes. The goal of both systems of kernel size separations is to achieve seed with acceptable appearance and plantability.

Kernel sizes may be length sized if the range in length would be unacceptable to customers. Length sizers, called uniflows, remove shorter kernels, utilizing a revolving indented cylinder. Shorter kernels ride up higher on the inside of the cylinder before falling out of the indentations

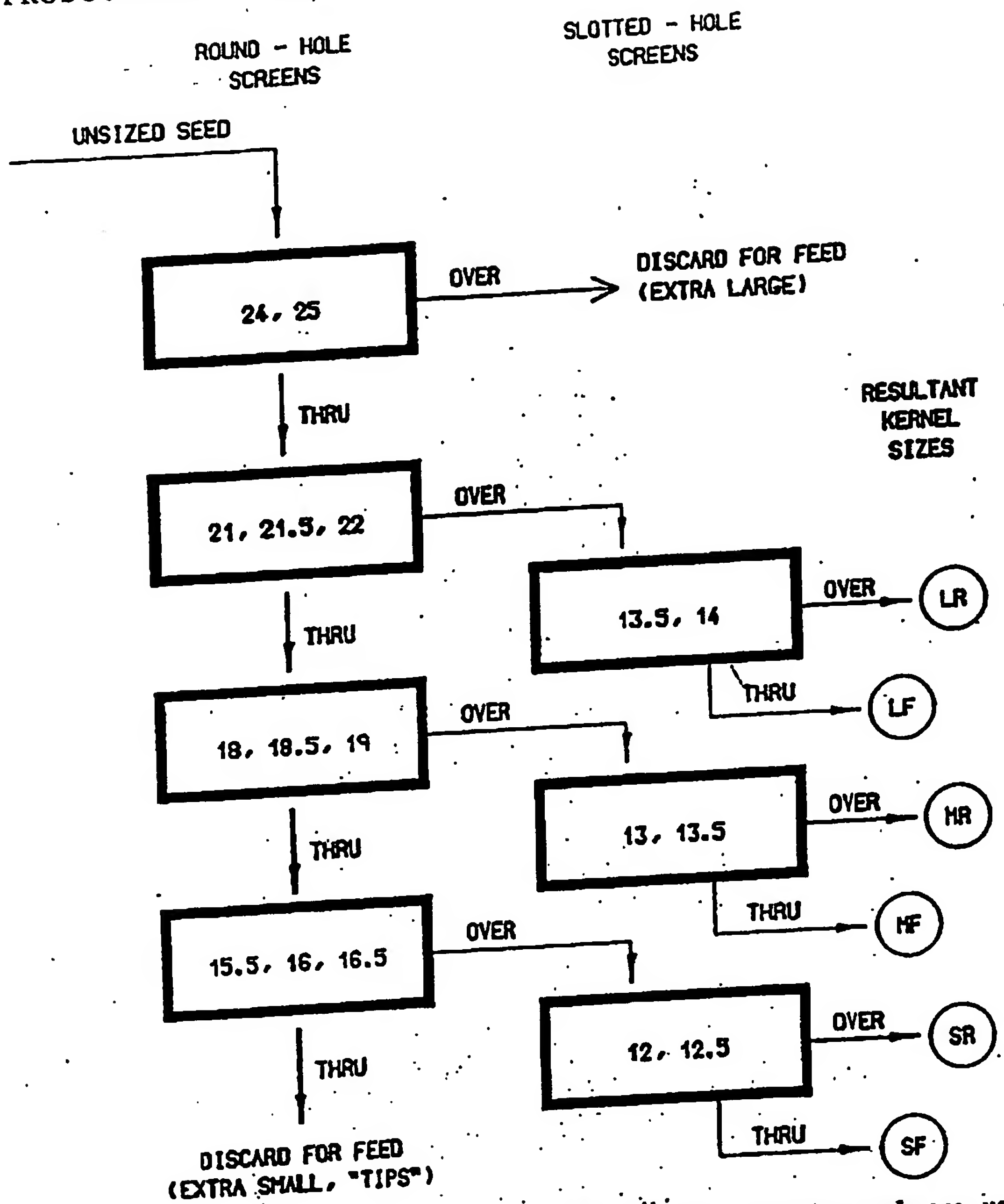

Fig. 9–12. A diagramatic outline of typical screen sizes used for sizing seed corn, using round-hole screens first and then dividing each portion (large, medium, and small) into flat and round kernels with slotted-hole screens. Screen sizes are given in 64ths of an inch.

and are captured by an adjustable tilt trough through the center of the cylinder. Uniflows may be used to remove long kernels in seed of three-way crosses and modified single crosses. Length sizing is much less common with seed from inbreds, which characteristically have rather short kernels. Length sizing generally has little effect on plantability if the shortest kernels are longer than one-half of the plate cell length.

Separation tolerances of 3/64 in. for width and thickness and 4/64 in. for length have been proposed (Bateman, 1972; McKee, 1963). The industry, however, commonly accepts a 4/64 in. range for kernel width

(round hole) and up to an 8/64 in. range for length with long kerneled seeds. Bateman (1972) suggested plantability (number of kernels dropped) tolerance with plate planters of 3% under-drop to 5% over-drop. This matches well with industry standards, but under-drop must be carefully monitored to be certain that sorting does not occur. Changing round hole screens by one-half 64th of an inch is usually sufficient to greatly improve plantabilities which are heavy or light.

Since the first "plateless" planter (John Deere® 'Max-Emerge'®) was introduced in the early 1970s, sizing methods have been undergoing change. This change has been accelerated as other equipment manufacturers have also introduced plateless planters. Each of these so-called plateless planters satisfactorily plant seed without prior separation of flat from round sizes. Consequently, most seed corn firms now offer plateless sizes (flats and rounds undivided or blended together), usually sized (and designated) further as large, medium, or small. Since variation in kernel length is no problem for these planters, the short kernels removed in length sizing are often blended into plateless sizes. Current estimates indicate that 85% or more of the corn in some areas is planted with plateless planters. Consequently, up to 60% of the sales of some companies is in plateless kernel sizes.

9–10.5.2 Cleaning Sized Seed

Removal of damaged and diseased kernels, which are usually lighter in weight than sound kernels, is accomplished through the use of aspirators or specific gravity separators. Aspirators have high capacity, but the separation is not as fine as with gravity separators. Consequently, aspirators tend to discard more desirable kernels without as thorough removal of imperfect seeds. Operation of gravity separators requires more skill, because adjustments must be made not only on the feed rate and air flow, but also on the tilt and pitch of the gravity deck and on shaker speed. Quality counts before and after cleaners are vital to satisfactory operation.

Conditioning of seed corn often has little effect on germination but appearance is greatly improved. Improved equipment and a higher comprehension of seed quality by discriminating customers has resulted in excellently conditioned seed being sold in the marketplace today.

9–10.6 Planter Plate Selection

Practically all seed corn companies offer planter plate suggestions for customer convenience. The process of making planter plate checks not only identifies the plates that should be suggested to the customer, but also serves as a check on the accuracy of sizing. If the check planter will not drop the seed accurately, adjustments are made on the sizing equipment to improve accuracy. Most plate selection is done on actual planter test stands provided in recent years by the DICKEY-john® Corp. Planter

stands are often electronically monitored, which makes this step faster and eliminates human error in counting drop accuracy. Planting suggestions are also made for plateless planters.

9-10.7 Treating the Seed

Most seed companies apply a fungicide or a combination fungicide/insecticide to the seed before bagging. The purpose of treating conditioned seed is to protect against seedling diseases and to give short-term protection against storage insects. Properly treating seed may also help offset vulnerability to disease caused by mechanical damage (Knake et al., 1986; Wortman and Rinke, 1951; Wright, 1948).

A typical dosage of the fungicide captan [*cis-N*-((trichloromethyl)thio)-4cyclohexene-1,2-dicarboximide] is about 0.6 g a. i. per kilogram of seed (600 ppm; 0.54 oz/bu). In areas where head smut disease is prevalent, Vitavax® or Vitavax®/thiram [bis(dimethylthio-carbamoyl)disulfide] fungicides are utilized in place of captan. A purplish or reddish dye is usually added to the fungicidal slurry to impart a distinctive color to the seed corn. This enables easy identification that treatment has been added. The treatment is spray metered on the seed in a rolling cylinder drum. A smooth uniform application is desired. During extremely cold weather, methanol may be added to prevent spotty treatment due to crystal formation.

Until recently, malathion (*O,O*-dimethyl phosphorodithoate of diethyl mercaptosuccinate) and methoxychlor [2,2-bis(p-methoxyphenyl)-1,1,1-trichloroethane] were the insecticides most commonly included in the treating mix. Use of these chemicals is now declining, due to efficacy and cost considerations, stricter governmental regulations, and the introduction of newer chemistries that are effective at lower application rates. Insecticide and fungicide use will continue to be a dynamic reflection of new chemistry, cooperative research between the chemical companies and the seed corn industry, and the regulation climate imposed by the Environmental Protection Agency and the Food and Drug Administration.

9-10.8 Bagging the Seed

Most seed corn today is packaged by automatic or semi-automatic equipment (Fig. 9-13). A specified amount of seed is weighed, the bag is hung and filled, a tag is sewn on, and the bag is coded. Only one or two operators are needed to monitor this operation and keep it running smoothly. Nearly all seed corn in the USA is packaged in multi-ply bags, most of which contain a moisture barrier of free polyethylene or a polyethylene-coated sheet to protect against external water. A crinkled outer ply with a nonslip coating improves handling and stacking ability.

A relatively new innovation is the replacement of sewing by the use of heat-sealed bags. The advantages of heat sealing are to: (i) make entry

Fig. 9-13. A typical bagging line in which the seed is weighed and dropped into the bag. Information such as bag weight, kernel size, and seed lot code is printed on the bag, and a preprinted tag is attached as the bag is sewn closed while traveling on a belt conveyor. The bags are subsequently stacked on pallets.

into the bag by moisture and insects more difficult; (ii) eliminate problems caused by malfunctioning sewing heads; and (iii) save the cost of sewing thread. Pressure sensitive labels which are preprinted by computers can be used in place of sewn in tags.

Package size has moved from the bushel bag (25 kg, or 56 lb) to units weighing 23 kg (50 lb) and, in recent years, to units with 80 000 kernels per bag. A problem with bagging all units with 80 000 kernels is that different kernel sizes neither weigh the same nor require the same volume. Bag weights may vary from 13 to 32 kg (30–70 lb) and a variety of bag sizes is necessary so that all bags will be full regardless of kernel size. In addition, palletizing bagged seed becomes difficult because of the different bag sizes. A partial solution to these problems has been achieved by some companies who have resumed varying kernel count per unit by kernel size, so that bag weight is near 22 kg (48 lb).

An important final step in conditioning is collecting and saving a representative sample of each seed lot. Trickle samplers are often used, but care must be exercised to ensure that the sampling tube draws from all the flow. Otherwise, stratification in the flow may cause the accumulation of a nonrepresentative sample. The sample thus obtained is used by quality assurance for germination and purity tests, verification of kernel counts, and checks for damaged kernels and inert material. State and federal laws require certain information to be printed on each bag or on a tag or label affixed to each bag. Requirements vary from state to

state, although attempts have been made to standardize these requirements.

9-11 QUALITY ASSURANCE

During the past 10 to 15 years, many changes have taken place in the techniques, equipment, and inbred parents that affect seed corn quality. Because of higher yield goals and increased production costs, farmers demand and, in general, receive high-quality seed. It is the goal of seedsmen to supply adequate quantities of a product that retains the genetic gains incorporated into a given hybrid by the corn breeder. To help realize these goals, most companies maintain a quality assurance program to monitor all phases of seed production.

The quality assurance program should have well-defined procedures and standards that are understood by all levels of management. Data should be collected according to rules and procedures outlined in *Rules of Testing Seeds* (Anonymous, 1981), the AOSCA *Certification Handbook* (Anonymous, 1971), and the *International Rules of Seed Testing* (Anonymous, 1985). Often more strict and precise rules and procedures have been adopted by company management.

Isolation standards and tests for genetic purity were described earlier in the chapter as they pertained to production of parent seed stocks and commercial hybrid seed corn (see p. 568–571, 573). The rest of this section deals with standards for specialty corn and quality assurance procedures that are conducted during and after conditioning.

9-11.1 Specialty Corn

Seed production and quality control procedures for maintaining genetic purity of white, waxy, high-lysine, and high-amylose corn are somewhat stricter than those outlined above for yellow dent corn. These specialty corns differ from normal yellow dent by being homozygous for recessive alleles at one or more critical loci. Thus, contamination arising from any foreign pollen would mask the expression of the desired trait.

Production standards are more demanding for specialty corn. Any expression of xenia in the kernels must be removed in order to meet genetic purity standards. Most waxy and high-amylose corn is marketed with <3% normal endosperm. See Bear (1975) for a discussion of purity requirements for these specialty corns.

Isolation standards to minimize contamination in specialty seed corn have been set at 201 m (660 ft) plus four border rows when the field size is 4 ha (10 acres) or less. The distance can be decreased as field size and/or the number of border rows increases. However, many commercial companies maintain the 201 m, and some require as much as 402 m (1320 ft), as a minimum isolation distance.

When contamination does occur, such as yellow kernels in white corn,

procedures have been established to remove the obviously impure seeds. The original method was to pick out the yellow kernels at the sorting tables before drying the ears. Although electronic devices sensitive to minute color changes can be used, the equipment is expensive and its capacity is limited, so few companies use color sorters. With waxy corn, a special technique to identify dent contamination is used (Jugenheimer, 1958). An iodine solution applied to exposed endosperm starch causes the waxy kernels to stain reddish brown, while normal-starch kernels stain blue-black. The iodine stain converts a chemical property to a color test that is ultimately equivalent to the detection of yellow kernels in the white seed.

9-11.2 Physical Quality

Physical quality is measured by the amount and kind of damaged kernels present and by the viability and vigor of the seed. These traits affect field emergence, establishment and uniformity, and ultimately yield (Knake et al., 1986; Wortman and Rinke, 1951; Wright, 1948; see Craig, 1977 for additional, older references).

Seed corn is said to be in its best physical condition when it has attained physiological maturity and is still in the field on the ear of the female parent plants. Many activities affecting physical quality are performed from the time the seed is harvested until it is planted by the customer. Seed left standing in the field after physiological maturity is subjected to conditions that lower quality, such as cold temperature, disease, and insect damage. Seed corn is subjected to mechanical damage during harvest, drying, shelling, cleaning, sizing, treating, and bagging. Isolating and identifying the source, nature, and extent of physical quality problems, and recommendation of preventive or corrective procedures, are responsibilities of quality assurance.

9-11.3 Sampling

Seed quality is measured by testing a representative sample of a lot or prescribed quantity of seed. Samples taken at all steps through the conditioning sequence are vital to the monitoring of seed quality. This is especially true if freezing temperatures have occurred in the field when moisture percentage of kernels exceeds the low temperature, measured in Fahrenheit degrees.

Samples should be large enough to enable running the desired test and a retest, if necessary. However, securing a new sample is usually preferable to retesting the original sample. Between the time the samples are collected and the quality tests are conducted, samples must be stored under conditions preserving the original quality as nearly as possible. Standard procedures for taking representative samples, and the necessary equipment needed, have been described (Anonymous, 1940, 1981; Justice, 1972).

9–11.4 Purity Analysis

Purity analysis for seed corn is done more for genetic purity than for determining percent of pure seed, as is practiced for quality control in small grains, soybean, and forage grasses. Beyond the endosperm purity and color checks described earlier for waxy and white hybrids, electrophoretic tests may be run to check for presence of selfs, outcrosses, off-types, or rogues. Although these tests are time consuming and expensive, they are quite accurate if the sample is representative and the isozymic patterns of the parents of the hybrid have been defined (Smith and Weissinger, 1984; Smith and Wych, 1986).

Maximum tolerances for genetic impurities have not been established by state or federal seed laws or seed certification agencies. Therefore in-house standards are employed by those seed companies that routinely conduct purity analyses. For single-cross hybrids, the presence of more than 5 to 6% selfs, or a combination of selfs and other off-types totaling 6 to 8%, are commonly used criteria for decisions to not offer a seed lot for sale. Growouts, however, might disclose that from 2 to 3% off-types would be neither detectable nor objectionable to customers, if the maturity, kernel color, and stature were similar to the hybrid. Alternatively, even 0.1% of taller off-type plants might generate considerable negative feedback from customers.

9–11.5 Germination

The germination test is the most frequently used procedure to measure product quality. Standard methods and guidelines for germination testing of seeds (Anonymous, 1981) and the necessary equipment and procedures (Justice, 1972) have been established. Most of the larger companies have established their own seed testing laboratories, but state, university, or private laboratories are also utilized.

Once a system has been established, accurate and consistent evaluation of the seedlings in the test is of greatest importance. The data collected constitute the germination percentage that is printed on the seed bag (usually on a sew-on tag), as required by both state and federal seed laws.

Standard germination tests are conducted under nearly ideal conditions; since field conditions seldom approximate the ideal, other tests have been developed to measure seed deterioration or vigor. Seed vigor is defined by the Association of Official Seed Analysts (AOSA) as "those properties which determine the potential for rapid, uniform emergence and development of normal seedlings under a wide range of field conditions" (Anonymous, 1983). Differences in vigor between two lots of seed that are otherwise genetically alike may not be obvious from percent germination in the standard warm test (Delouche, 1973; Pollock and Roos, 1972).

9-11.5.1 Cold Test

Most seed companies use some type of cold test as a routine test for vigor. The most commonly used procedures have been reviewed elsewhere (Anonymous, 1983; Martin and O'Neil, 1987; McDonald, 1975). Craig (1977) stated that cold test results indicated the ability of seed to emerge when soil conditions are cold and wet and may reflect the amount of mechanical damage a seed lot has undergone. Currently, however, uniform procedures and agreement on the value of the cold test as a measurement of quality do not exist in the seed industry. Burris and Navratil (1979) discussed the variability inherent in various cold test procedures and the consequent lack of comparability of results from one laboratory to another. Cold testing using one established technique within each seed company may nevertheless be useful for judging seed lots as to suitability for sale following carryover storage conditions, early freezes, etc.

9-11.5.2 Tetrazolium Test

This biochemical test with 2,3,5-triphenyltetrazolium chloride quickly identifies seed viability. Enzymatic activity in living tissue turns the colorless tetrazolium red; loss of enzymatic activity in dead tissue leaves the tetrazolium colorless. The tetrazolium test is further used to evaluate internal seed injury, insect injury, frost damage, and viability of dormant seed (Bennett and Loomis, 1949; Goodsell, 1948; Moore, 1958; Porter et al., 1947).

9-11.5.3 Accelerated Aging Test

In the accelerated aging test (sometimes called the *rapid aging test*), seeds are stressed prior to the germination test (Anonymous, 1983). The conditions suggested by the AOSA for seed corn are to expose the seed to nearly 100% relative humidity at 42 °C (108 °F) for 96 h. The percentage survival is an index for longevity of seed viability in storage and a good measure of seed vigor.

9-11.5.4 Electrical Conductivity Test

Electrical conductivity of steep water (seed leachate) has been studied as an index of seed quality, but has not yet received widespread use because of procedural variability.

9-12 STORAGE AND DISTRIBUTION

9-12.1 Storage

The basic requirements for seed storage space are that it be dry, free of rodents and grain storage insects, and capable of being held within

certain temperature limits (Airy, 1955). Seed is at its highest quality level at physiological maturity and can only deteriorate from that point onward. The goal of seed storage is to maintain physiological quality throughout the storage period by minimizing deterioration. The best storage conditions can only maintain quality.

Storage for both bulk and bagged seed is necessary (Fig. 9–14). In some companies, facilities have been designed to take advantage of the same space for both. As the bulk seed is moved out for conditioning, the bagged seed can be moved into the vacated storage areas. At most facilities, however, the total volume of seed that must be stored exceeds bulk storage capacity; therefore, some seed must be bagged and moved to warehouse storage (often cold storage) to allow the completion of conditioning. Stored bagged seed is normally palletized and moved with forklift trucks (Fig. 9–14).

Storage of seed corn, either bulk or bagged, for prolonged periods at temperatures above 10 °C (50 °F) leads to deterioration of seed quality. For this reason, bulk seed should be cooled after the drying and shelling steps. This is usually accomplished by aeration of bulk bins with ambient air. Further, surplus bagged seed should be stored during the summer at or below 10 °C and at relative humidity levels between 45 to 55% to maintain the desired moisture content and seed quality. Early work (Airy, 1955; Sayre, 1948) indicated the influence of reduced temperature and moisture level on the maintenance of quality and longevity of stored

Fig. 9–14. Bagged seed corn in storage on pallets in preparation for distribution to sales representatives. Some seed companies now use a "stretch wrap" machine that automatically surrounds the pallet of seed corn with a protective plastic wrapping prior to storage and/or shipment. Forklift trucks are used to move pallets around the warehouse.

seed. Specifications for equipment and buildings for controlled atmosphere storage and its effects on stored seed have been reported (Beck, 1969; Dahlberg, 1967; Stanfield, 1971, 1972).

Hybrid seed corn companies must produce seed supplies over and above that which market forecasts indicate will be sold in the subsequent sales year. Some carryover seed, as this unsold seed is called, is desired as insurance against unpredictable consequences of weather, government programs, etc. Seed companies normally anticipate growing approximately 30 to 40% more seed than estimated sales requirements, to fill supply channels and to hedge against possible reduced yields from production acreage. A recent example illustrates how this practice benefits North American agriculture. The 1983 seed corn production acreage in the USA was substantially lower than in previous years, in anticipation of the impact of the federal government's PIK program on 1983 seed sales and anticipated carryover. However, drought reduced 1983 seed field yields severely in many production areas. Seed supplies for the 1984 planting season would have been critically short had it not been for adequate quantities of high-quality carryover seed inventoried in controlled-atmosphere warehouses.

9–12.2 Sales and Distribution

There are basically two common methods of sales and distribution of seed corn from the production plant or warehouse to the customer. The method used most widely throughout the Corn Belt involves farmers serving as farmer-dealers (or sales representatives or sales agents). The second method, involving seed distributors and/or dealers, is more common where corn acreage is less concentrated.

As the name implies, the farmer-dealer or sales representative is usually a farmer who is also a part-time salesman. This method of distribution depends on the local sales representative to: (i) call on his neighboring farmers to solicit their business: (ii) write the order; (iii) receive and store the seed until delivery; (iv) arrange for pick up or delivery; (v) complete the sale and collect the account; (vi) arrange for return of unsold seed to the production plant or warehouse; and (vii) provide service to the customer as needed. The sales representative is usually under the supervision of full-time company employees, commonly referred to as district sales managers. In the author's company, the sales representative never takes actual ownership of the seed corn.

In contrast, a seed distributor or a seed dealer purchases the seed corn from the seed company, and in turn sells the seed to other dealers and/or to farmer customers. Seed may be sold by the seed company directly to a seed dealer, bypassing the seed distributor. Alternatively, seed may be sold to a distributor who in turn sells it to one or more seed dealers. The dealer is often employed in related agricultural endeavors, such as fertilizer or chemicals, other seeds, livestock feeds, farm supply

stores, or elevator operators. This method of operation is especially adapted to areas where sales volumes are not great enough to justify the farm-to-farm calls of the local salesman, but are compatible with the existing business of the store or elevator.

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Marker-assisted backcrossing: a practical example

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Summary

That molecular markers allow fast recovery of recurrent parent genotype in backcross programs is undisputed. Restriction Fragment Length Polymorphisms (RFLP's) were used in maize to introgress by backcross a transgene construct, containing phosphinothricin resistance and insecticidal protein genes, from a transformed parent into an elite inbred line. At each generation plants carrying the transgene construct were selected based on their phosphinothricin resistance, and further characterized with RFLP's. Both maximum recovery of recurrent parent genotype and minimum linkage drag were taken into account for marker-based selection. Embryo rescue was used to shorten generation time. Progress towards recurrent parent genotype was spectacular. Levels of recurrent parent genotype recovery which would normally be observed, in the absence of selection, in the BC_6 generation were obtained at the BC_3 generation, about one year after BC_1 seeds had been planted. Besides the evidence already provided by RFLP's, phenotypic evaluation of the backcross-derived near-isogenic lines will constitute an additional check of the completeness of the conversion.

Introduction

Backcrossing has been a common breeding practice for as long as elite germplasm has been available. It has mainly been used to introgress single Mendelian traits, such as disease resistances or quality factors, into elite germplasm (Allard 1960; Hallauer and Miranda 1981). One of the most attractive attributes of backcrossing is that it allows to perform targeted modifications without disrupting the existing overall genetic balance of the recurrent parent.

However, production of fully converted near isogenic lines through classical backcrossing procedures is a lengthy procedure, if at all possible. Theoretically, a minimum

of seven classical backcross generations are required to recover more than 99% of recurrent parent genotype, assuming no linkage drag. The attractiveness of classical backcross procedures is therefore substantially diminished for crops, such as maize (*Zea mays* L.), where the turn-over of elite cultivars is very fast. In addition, full recovery of recurrent parent genotype is usually not achieved through classical backcrossing, which may result in deleterious agronomic effects. Murray *et al.* (1988) reported about 90% recurrent parent genotype recovery in two BC_{10}-equivalent conversions (A632Ht and A632Rp) of the maize line A632. The conversions had retained respectively 4 and 7 donor fragments in addition to the one carrying the gene of interest.

Reduction in the number of backcross generations needed to obtain fully converted individuals has been shown theoretically, or from simulations, to be achievable through the use of molecular markers (Tanksley *et al.* 1989; Hospital *et al.* 1992; Jarboe *et al.* 1994). Because they provide thorough characterization of the genetic variability at each backcross generation, markers allow to take full advantage of this variability by applying the highest possible selection intensity.

Efficiency of marker-assisted backcrossing was investigated through an experiment aimed at introgressing a single genetic factor (a transgene construct) from a donor into a recipient maize line.

Materials and methods

Plant Material

A bemizygous transgenic maize line of Lancaster origin was used as donor parent to introgress its transgene construct, through repeated backcrossing, into a recipient parent from the Stiff Stalk germplasm group. Both parents are proprietary elite lines. The transgene construct carries both a phosphinothricin resistance gene and synthetic genes encoding the entomotoxic fragment of the CryIA(b) *Bacillus thuringiensis* protein (Koziel *et al.* 1993). Transformation was achieved through microprojectile bombardment (Koziel *et al.* 1993) and resulted in a single insertion (*Bt* locus), on chromosome 1 (Figure 1).

Backcross protocol

The F1 progeny of the cross between the donor and the recipient was screened for the presence of the transgene construct by applying Basta, a phosphinothricin-based herbicide, onto each plant. Resistant individuals were then used to generate BC_1 progeny.

For each backcross generation, except the BC_4, individuals were planted in multipots and sprayed with Basta to eliminate those which did not carry the transgene construct. To avoid the stress resulting from treatment with Basta, BC_4 plants carrying the transgene construct were identified using Southern blots probed with the *pat* and *Bt* genes. Resistant plants were transplanted in an open-soil greenhouse and leaf-sampled for molecular marker

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Selection procedure

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Results and discussion

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analyses. Results of marker analyses were made available at the latest two weeks after flowering. A single plant was selected, of which all backcross-derived embryos were rescued and transferred onto tissue culture medium. Plantlets that developed from these embryos first underwent a greenhouse acclimation phase, while still growing on tissue culture medium, before being transplanted into multipots. Backcross cycles lasted, on average, four months.

Molecular marker analyses

Restriction Fragment Length Polymorphisms (RFLP's) were used to establish genotypes in all four generations. RFLP detection involved either radioactive or chemiluminescent techniques. For the BC_1 generation, 61 marker-enzyme combinations were chosen from among those revealing polymorphism between donor and recipient. They provided coverage of the entire genome, defining intervals of about 25 cM in size, and contained two loci tightly linked to the *Bt* locus, CG320 and CG415, respectively 5 and 16 recombination units away (Figure 1). For subsequent generations, markers analyzed in the BC_{n+1} generation comprised both those for which the selected BC_n plant was heterozygous, or tightly linked ones, and additional ones located in chromosomal segments for which the selected BC_n plant was heterozygous (Table 1). Marker map positions were obtained from independent reference populations and confirmed by analysis of segregation in the BC_1 generation.

Selection procedure

At each generation plants were ranked based both on the percentage of homozygous recurrent-parent-genotype and on the extent of linkage drag around the *Bt* locus, in an attempt to integrate both criteria. Plants for which two or more adjacent markers had missing values were not included in the analyses. Success or failure of the pollinations also contributed to the selection procedure. One single plant was selected at each generation: the best ranking one of those for which a backcross progeny of size 100 or more (50 or more for the BC_3 selection) was available.

Results and discussion

Selection for the gene of interest

The observed segregation ratios for phosphinothricin resistance (Table 1) were not significantly different ($P<0.05$) from the expected 1:1, as shown by Chi-square tests.

Recurrent parent genotype recovery

Statistics for the genotyped plants are summarized in Table 1. Calculations were performed taking the whole genome into account, including the *Bt* locus. The "perfect" backcross-derived plant therefore counts one heterozygous chromosome segment, that

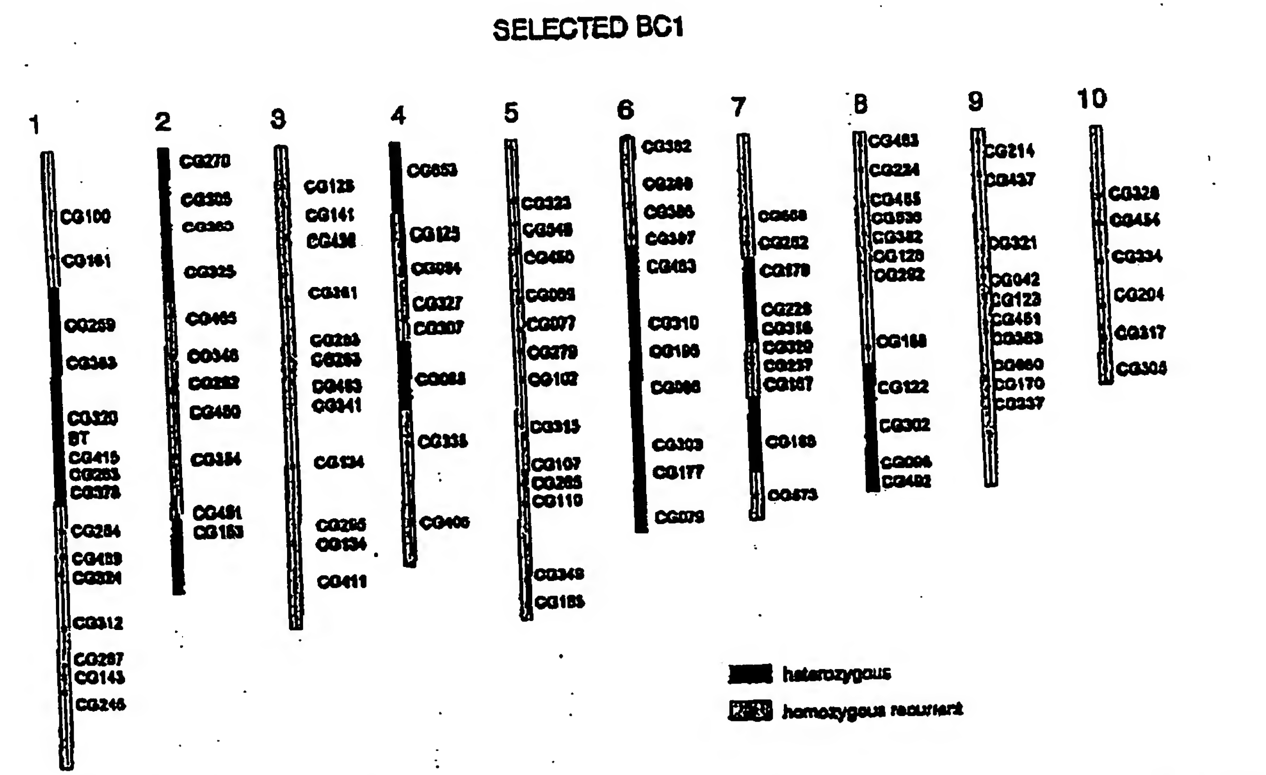
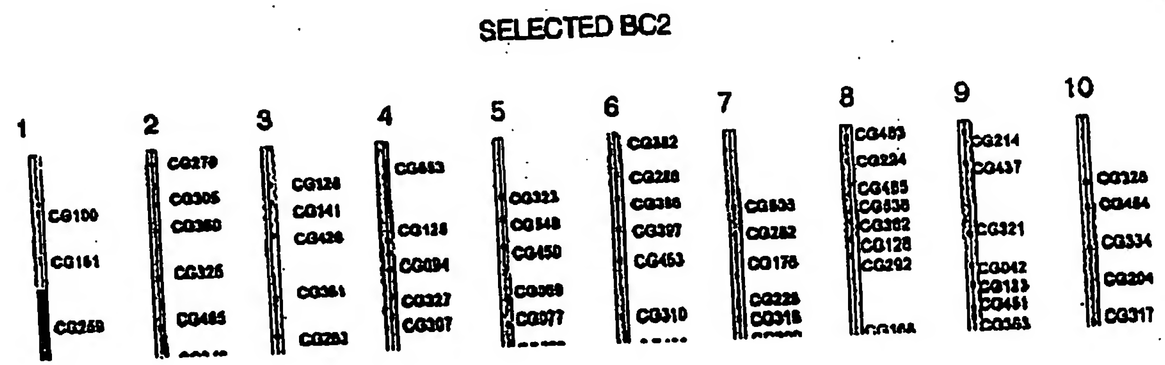
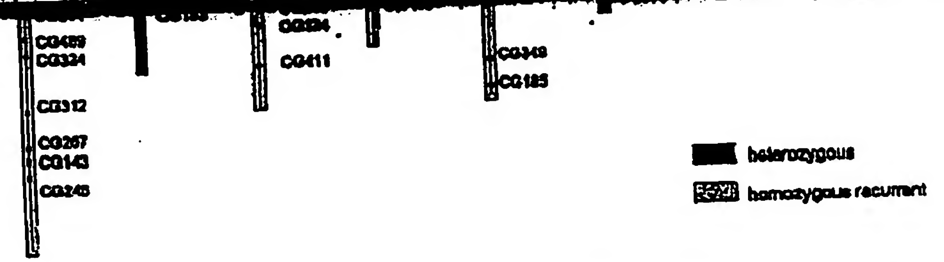


Figure 1-a: Genetic maps of the backcross-derived individuals selected in the first four generations of a marker-assisted backcross program. The locus to be introgressed (*Bt*) is located on chromosome 1.





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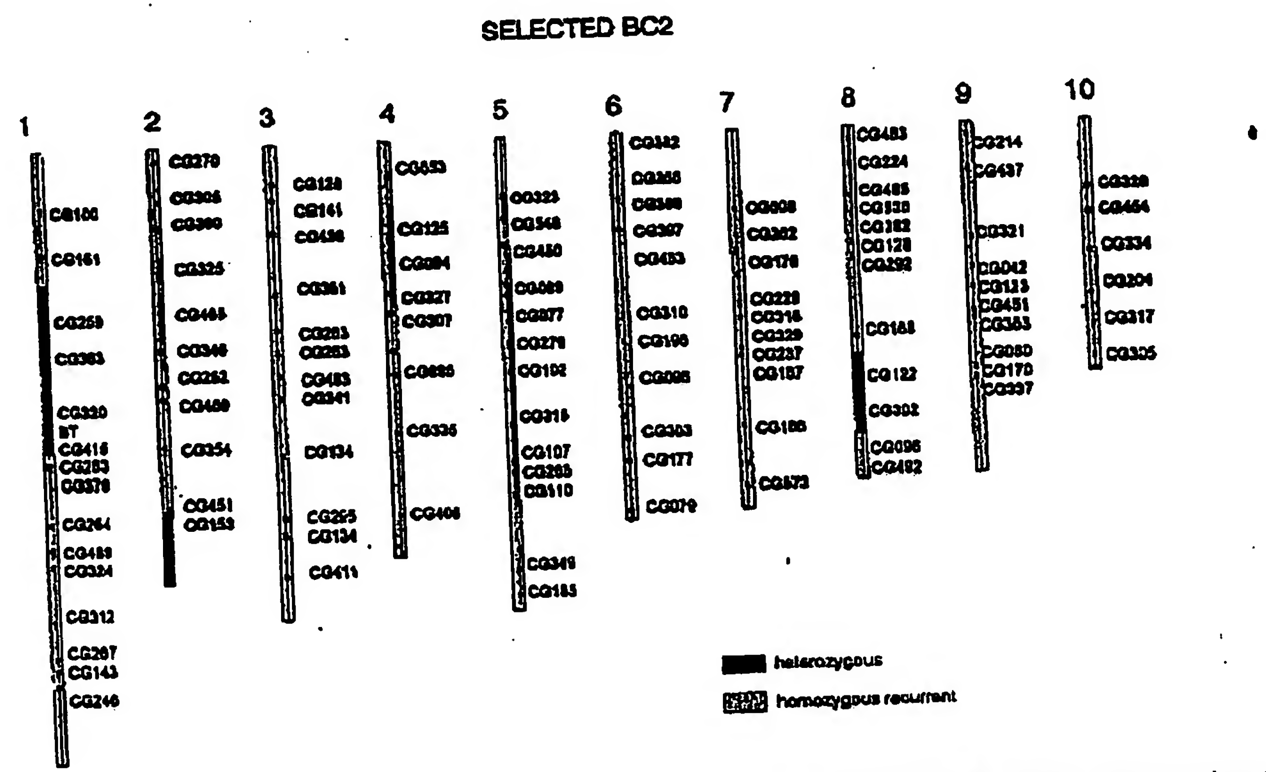


Figure 1-b: Genetic maps of the backcross-derived individuals selected in the first four generations of a marker-assisted backcross program. The locus to be introgressed (*Bt*) is located on chromosome 1.

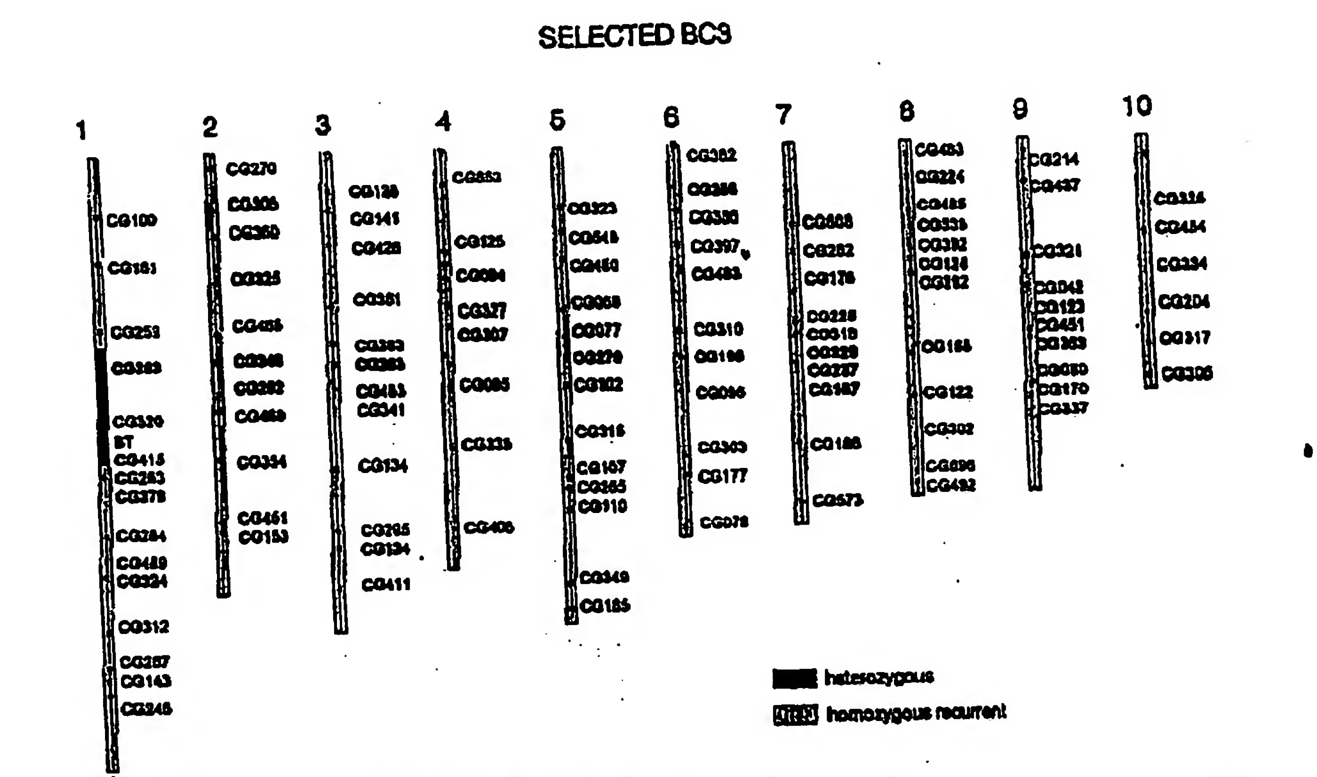
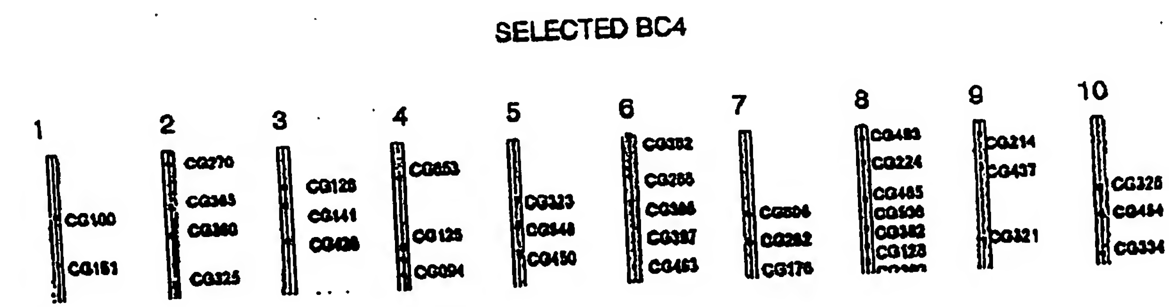
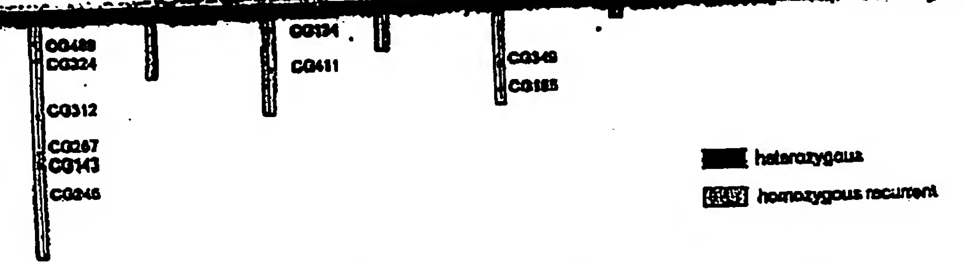


Figure 1-c: Genetic maps of the backcross-derived individuals selected in the first four generations of a marker-assisted backcross program. The locus to be introgressed (*Bt*) is located on chromosome 1.





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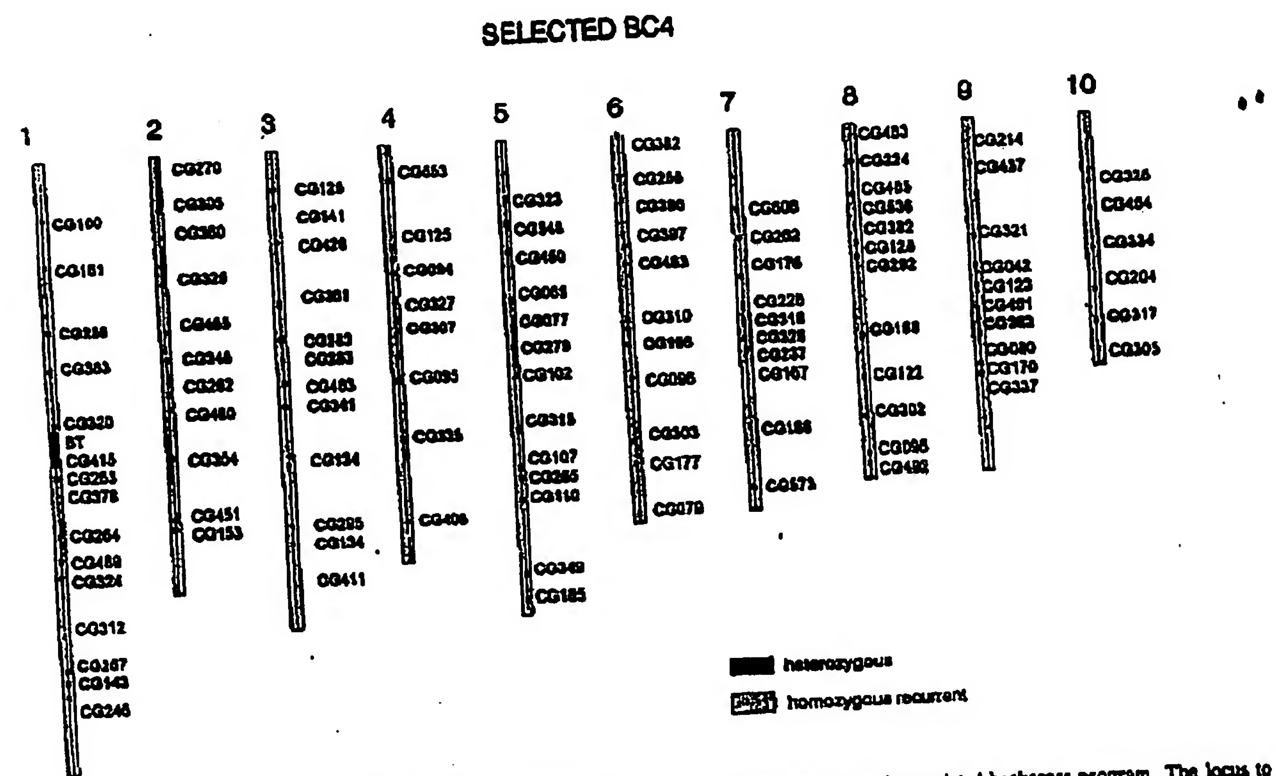

Figure 1-d: Genetic maps of the backcross-derived individuals selected in the first four generations of a marker-assisted backcross program. The locus to be introgressed (*Bt*) is located on chromosome 1.

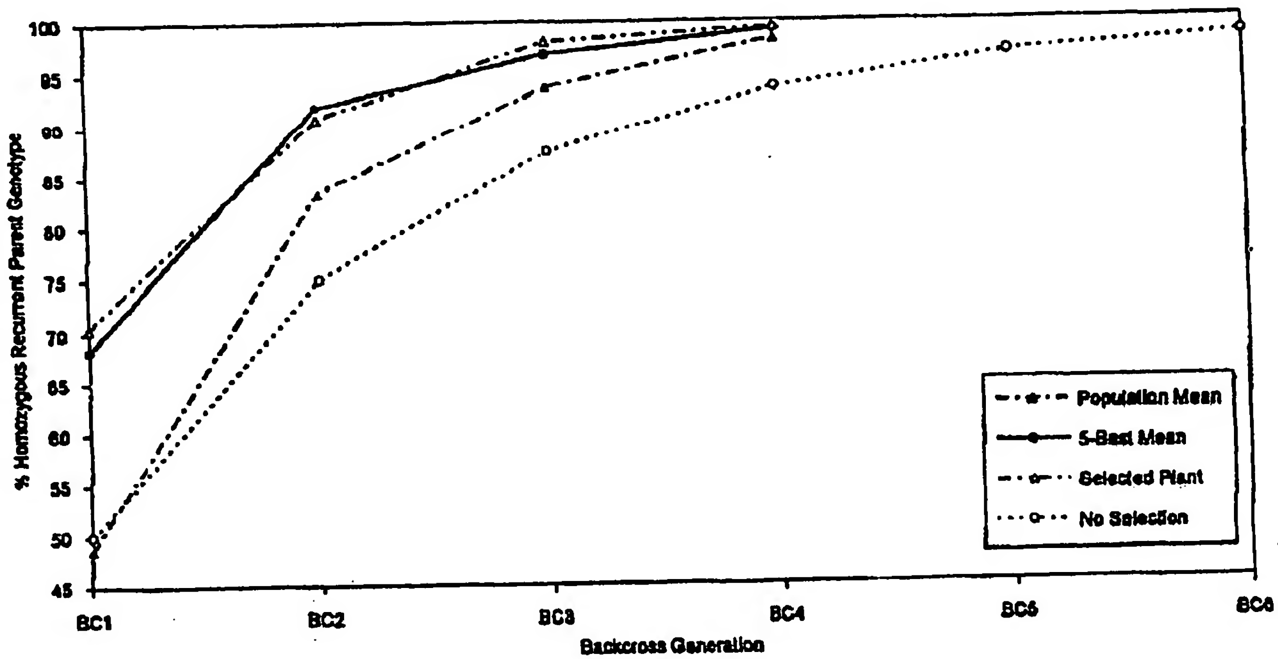

Figure 2: Recovery of recurrent parent genotype through backcrossing, with or without marker-assisted selection

Table 1: Proportion and characteristics of plants carrying the genes of interest, in the first four generations of a marker-assisted backcross program.

generation	% phosphinothricin	RFLP genotyping	nb plants	% homozygous recurrent	nb heterozygous ...

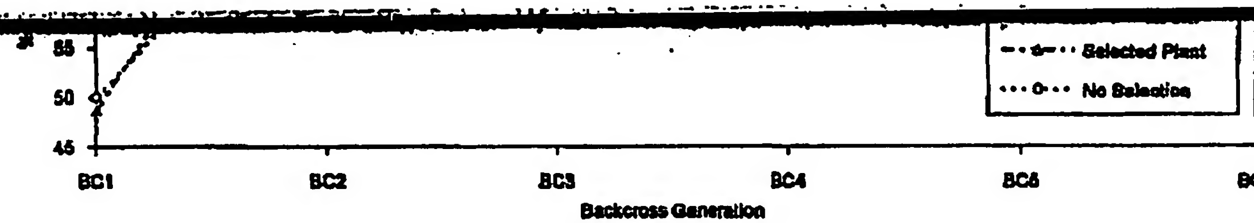

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Table 1: Proportion and characteristics of plants carrying the genes of interest, in the first four generations of a marker-assisted backcross program.

generation	% phosphinothricin resistant plants	RFLP genotyping			nb plants analyzed *	% homozygous recurrent parent genotype				nb heterozygous chromosome segments ***			
		nb plants	nb loci	nb datapoints		mean	std dev	5-best mean **	selected plant	mean	std dev	5-best mean **	selected plant
BC1	49.05	96	61	5856	87	48.72	10.35	88.31	70.45	11.01	2.17	7.75	6
BC2	44.65	61	22	1342	90	83.42	5.64	91.98	90.84	5.03	1.64	3.20	3
BC3	46.32	72	10	720	71	93.63	1.85	96.82	98.03	2.20	0.71	1.60	1
BC4	-	26	3	78	26	98.23	0.49	99.09	99.36	1.00	0.00	1.00	1

* Plants for which two or more adjacent markers had missing values were not included in the analyses

** Mean value of the five individuals having the five highest percentages of homozygous recurrent parent genotype.

*** including the segment carrying the transgene construct.

comprising the *Bt* locus. It also displays 99.36% of homozygous recurrent-parent-genotype. The remaining 0.64% corresponds to the average relative length of the chromosome segment containing the *Bt* locus, which depends on the two flanking markers chosen.

The mean percentage of homozygous recurrent-parent-genotype of the BC_1 generation was slightly lower than the expected 50%. This can be explained by linkage drag around the *Bt* locus, given that this percentage was computed based only on plants selected for heterozygosity at the *Bt* locus. For all other backcross generations the mean percentage of homozygous recurrent-parent-genotype was much higher than what would have been observed, should no selection have been done (Figure 2).

The percentage of homozygous recurrent-parent-genotype of the selected plant (Table 1) and the average of the five largest values (Table 1) were always very similar to one another, and much superior to the population mean value (Figure 2). The percentage of homozygous recurrent-parent-genotype of the selected plant was found only once, in the BC_2 generation, to be smaller than the average of the five largest values. This corresponded to the only time when the selected plant was not the one with the maximum percentage of homozygous recurrent-parent-genotype. The plant had been selected because it displayed a favorable recombination on one side of the *Bt* locus (Figure 1).

The percentage of homozygous recurrent-parent-genotype of the selected BC_1 plant was almost equal to that of an unselected BC_2, that of the selected BC_2 was larger than that of an unselected BC_3, that of the selected BC_3 was barely smaller than that of an unselected BC_6, and that of the selected BC_4 was equal to that of the "perfect" backcross-derived plant, given the set of markers that was used. Such rates of recurrent parent genotype recovery are consistent with results of simulation analyses. Jarboe *et al.* (1994) who used the maize genome as a model reported that three backcross generations and 80 markers were needed to recover 99% of recurrent parent genotype.

Number of donor chromosome segments

The number of heterozygous chromosomal segments decreased from one backcross generation to the next. Plants selected at each generation were not necessarily those which had the lowest number of heterozygous chromosomal segments (Table 1). However, with the set of markers used, BC_3 and BC_4 plants were recovered which contained only one heterozygous chromosomal segment: that comprising the *Bt* locus.

Linkage drag

Linkage drag around the *Bt* locus was estimated, relative to the length of chromosome 1. Its value was found to lie between 24.0 and 48.4% for the selected BC_1 individual, between 17.6 and 34.8% for the selected BC_2, between 2.0 and 24.0% for the selected BC_3, and between 0.0 and 8.4% (respectively 0.0 and 14.5 cM) for the selected BC_4.

The two values given for each ge
correspond to extreme positions o
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BC_4 is likely to be less than 1.3%
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Conclusion

These results clearly demonstr
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Comparison of BC_4-derived
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14.5 cM) for the selected BC_4.

The two values given for each generation are extreme values of linkage drag, which correspond to extreme positions of the crossing-overs in the marker-defined intervals flanking the transgene construct locus. Therefore the true linkage drag value of the selected BC_4 is likely to be less than 1.3% of the genome. Although this maximum value may appear to be somewhat high, reflecting the limited selection pressure put here on linkage drag, it is much lower than what would be expected from classical backcross programs (Stam and Zeven 1981; Tanksley *et al.* 1989). Practically, in a study of *Tm*-2 conversions of tomato cultivars obtained by a large number of classical backcross cycles, Young and Tanksley (1989) found that the sizes of the introgressed fragments ranged between 4 and 51 cM.

Conclusion

These results clearly demonstrate that molecular markers provide important time and quality advantages over classical procedures for the production of near-isogenic lines through backcrossing. Only four backcross generations were necessary to recover, in less than a year and a half from planting of the BC_1's, individuals which appeared to be genotypically fully converted. Nevertheless, it is likely that recovery of recurrent parent genotype could proceed even faster than in the experiment described herein, should the appropriate protocol and resources (population size, number and position of markers) be allocated.

Comparison of BC_4-derived lines with the recurrent parent for both morphological markers and agronomic performance (including hybrid performance) will be performed in order to confirm the completeness of the conversion.

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Exhibit 6: Openshaw *et al.*, (1994) Marker-assisted Selection in Backcross Breeding, Analysis of Molecular Marker Data

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Marker-assisted Selection in Backcross Breeding

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Abstract. The backcross breeding procedure has been used widely to transfer simply inherited traits into elite genotypes. Genetic markers can increase the effectiveness of backcrossing by 1) increasing the probability of obtaining a suitable conversion, and 2) decreasing the time required to achieve an acceptable recovery. Simulation and field results indicated that, for a genome consisting of ten 200-cM chromosomes, basing selection on 40 or 80 markers in 50 BC individuals that carry the allele being transferred can reduce the number of backcross generations needed from about seven to three.

The backcross breeding procedure has been used widely to transfer simply inherited traits into elite genotypes. Usually, the trait being transferred is controlled by a single gene, but highly heritable traits that are more complexly inherited have also been transferred successfully by backcrossing; for example, maturity in maize (Rinke and Sentz, 1961; Shaver, 1976). Today, backcrossing is being used to transfer genes introduced by such techniques as transformation or mutation into appropriate germplasm.

Several plant breeding textbooks give good descriptions of the backcross procedure (Allard, 1960; Fehr, 1987). A donor parent (DP) carrying a trait of interest is crossed to the recurrent parent (RP), an elite line that is lacking the trait. The F_1 is crossed back to the RP to produce the BC_1 generation. In the BC_1 and subsequent backcross generations, selected individuals carrying the gene being transferred are backcrossed to the RP. The expected proportion of DP genome is reduced by half with each generation of backcrossing. Ignoring effects of linkage to the selected DP allele being transferred, the percentage recurrent parent (%RP) genome expected in each backcross generation is calculated as:

$$\%RP = 100\,[1 - (0.5)^{n+1}]$$

where n is the number of backcrosses.

Backcrossing of selected plants to the RP can be repeated each cycle until a line is obtained that is essentially a version of the RP that includes the introgressed allele. After six backcrosses, the expected recovery is >99% (Table 1).

Until recently, discussions of the recovery of the RP genome during backcrossing have emphasized the expected values for %RP shown in Table 1, and have largely ignored the genetic variation for %RP that exists around the expected mean. With the development of genetic markers capable of providing good genome coverage, there has been interest in taking advantage of that variation to increase the efficiency of backcrossing.

Selection for RP marker alleles can increase greatly the effectiveness of backcross programs by allowing the breeder to 1) select backcross plants that have a higher proportion of RP genome, and 2) select backcross individuals that are better conversions near a mapped donor allele being transferred (i.e., select for less linkage drag). Expressed in practical terms, using genetic markers to assist backcrossing can 1) increase the probability of obtaining a suitable conversion, and 2) decrease the time required to achieve an acceptable recovery.

Issues to consider when planning a marker-assisted backcross program include 1) the time advantage of using markers to assist backcrossing, 2) the number of markers needed, and 3) the number of genotypes to evaluate. In this report, we use results from previous literature, computer simulation, and empirical studies to provide some guidelines.

Table 1. *Expected recovery of recurrent parent (RP) genome during backcrossing, assuming no linkage to the gene being transferred.*

Generation	%RP
F_1	50.0000
BC_1	75.0000
BC_2	87.5000
BC_3	93.7500
BC_4	96.8750
BC_5	98.4375
BC_6	99.2188
BC_7	99.6094

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Materials and methods

The maize genome was the model for the simulation. The simulated genome contained ten 200-cM chromosomes. Simulation of crossing over was based on a Poisson distribution with a mean of 2.0 ($\lambda = 2$) (Hanson, 1959), which, on average, generated one cross over for every 100-cM length. The simulations reported here assume no interference. Codominant genetic markers were evenly distributed in the genome and sites of the donor gene were randomly assigned to genome locations.

Simulations were conducted with the following parameters:

Number of progeny: 100 or 500.
Backcross generations: BC_1, BC_2, and BC_3.
Number of markers: 20, 40, 80, or 100.
Number selected to form the next BC generation: 1 or 5.

Selection was based on 1) presence of the donor allele and 2) high %RP). %RP was calculated as the average of the (one or five) selected individuals. Values presented are the mean of 50 simulations.

Results

In the computer simulation study, all methods modeled greatly increased the speed of recovering the RP genome compared to the expected recovery with no marker-assisted selection (compare Tables 1 and 2). At least 80 markers were required to recover 99% of the RP genome in just three BC generations (Table 2). Use of at least 80 markers and 500 progeny allowed recovery of 98% RP in just two BC generations. Response to selection was diminished only slightly by spreading the effort over five selections. Using markers, the number of backcross generations needed to convert an inbred is reduced from about seven to three.

By the BC_3 generation, there appears to be no practical advantage to using 500 vs. 100 individuals. If the presence of the donor trait in the backcross individuals can be ascertained before markers are genotyped, then only half the number of individuals indicated in the tables will need to be analyzed.

When a small number of markers are used, they quickly became non-informative; i.e., selection causes the marker loci to become fixed for the RP type before the rest of the genome is fully converted (Table 3; Hospital et al., 1992). This situation was most prominent in the larger populations, where a higher selection intensity placed more selection pressure upon the marker loci. Accordingly, it is of interest to consider how closely the estimation of %RP based on markers reflects the actual genome composition. The combination of estimation of %RP based on fewer markers and subsequent selection tends to bias the estimates upward (compare Tables 2 and 3).

The results from the simulation compare well with real field data. In a typical example, 50 BC_1 plants carrying the gene being transferred were genotyped at 83 polymorphic RFLP loci (note that this corresponds to a population size of 100 unselected plants in Tables 2 and 3). The five best BC_1 recoveries had estimated %RP values of 85.9%, 82.7%, 82.0%, 81.4%, and 81.2%. After evaluating 10 BC_2 plants from each selected BC_1, the best BC_2 recovery had an estimated %RP of 94.6%.

Discussion

The simulations (Table 2; Hospital et al., 1992) and our experience indicate that four markers per 200-cM chromosome is adequate to greatly increase the effectiveness of selection in the BC_1. However, using only four markers per 200 cM will likely make it very difficult to map the location of the gene of interest. Adequate summarization of the data is an important

Table 2. *Percent recurrent parent genome during marker-assisted backcrossing.*

Generation	100 Progeny No. markers 20	40	80	100	500 Progeny No. markers 20	40	80	100
			One selected					
BC_1	84.5	84.5	84.2	88.0	89.9	90.7	90.2	90.5
BC_2	95.0	95.2	95.8	97.2	96.5	97.7	98.5	98.6
BC_3	97.4	97.6	98.9	99.2	97.7	98.3	99.4	99.5
			Five selected					
BC_1	82.9	85.1	84.9	84.7	87.7	88.1	88.9	88.9
BC_2	93.7	95.0	95.8	95.7	95.5	96.8	97.8	97.9
BC_3	97.1	98.9	98.8	98.9	97.3	98.3	99.3	99.3

Table 3. *Estimates of percent recurrent parent genome, based on marker loci.*

Generation	100 Progeny No. markers 20	40	80	100	500 Progeny No. markers 20	40	80	100
			One selected					
BC_2	98.7	97.8	95.6	97.2	100.0	99.1	98.6	98.0
BC_3	100.0	99.8	99.3	99.5	100.0	100.0	99.9	98.2
			Five selected					
BC_2	96.4	96.5	96.2	95.8	100.0	98.5	98.3	98.2
BC_3	99.9	99.8	99.5	99.1	100.0	100.0	99.9	99.8

part of a marker-assisted backcross program. Ideally, the markers used can supply data that can be represented as alleles of loci with known map position. Estimation of %RP, mapping the position of the locus of interest, and graphical display of the results (Young and Tanksley, 1989) are all useful in understanding and controlling the specific backcross experiment being conducted.

It appears that, with the use of genetic markers, the portion of the RP genome that is not linked to the allele being transferred can be recovered quickly and with confidence. The recovery of RP will be slower on the chromosome carrying the gene of interest. A considerable amount of linkage drag is expected to accompany selection for the DP allele in a backcross program. For a locus located in the middle of a 200-cM chromosome, the length of the DP chromosome segment accompanying selection is expected to be 126, 63, and 28 cM in the BC_1, BC_3, and BC_7 generations, respectively (Hanson, 1959; Naveira and Barbadilla, 1992). Our observations support the recommendation of Hospital et al. (1992) that preference be given to the selection for recombinants proximal to the allele of interest, but that selection for recovery of the RP elsewhere in the genome also be considered. This two-stage selection can probably be done quite effectively ad hoc by the breeder once the data is adequately summarized; however, Hospital et al. suggest ways to incorporate the two criteria into a selection index such that each component of selection is assured appropriate weighting.

Use of genetic markers can greatly increase the effectiveness of backcrossing, and they should be used in any serious backcrossing program if resources are available to the breeder.

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Exhibit 7: Hallauer *et al.* (1988) Corn Breeding, Corn And Corn Improvement, No. 18, p. 472

Included in the Information Disclosure Statement filed by Applicant in the present case. First cited by Applicant in March 11, 2003 Amendment, p. 25 in the parent application, 09/758,713, issued as U.S. Patent No. 6,720,487. The Examiner's May 23, 2003 Office Action as entered in response to the Amendment.

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8 Corn Breeding[1]

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Corn (*Zea mays* L.) breeding for hybrid development was begun in the early 1900s with the work of Shull (1909), East (1908), and others, but a primitive type of breeding was conducted for thousands of years by the American Indians before the European colonists began settlement in the New World. The U.S. Corn Belt dents were derived from crosses that included germ plasm of the northeastern flint and southern dent or gourd-seed types, beginning about 1850, with subsequent selection that developed the U.S. Corn Belt dents. Open-pollinated cultivars, such as Reid Yellow Dent, Krug, Leaming, and Lancaster Sure Crop were developed by a type of mass selection that was based on plant, ear, and grain type. This early work, which was done primarily by farmers and seedsmen, provided the germplasm sources from which were developed the inbred parental lines that were used to produce the first double-cross hybrids used in the USA. Even to the present time, relatively little germ plasm from other countries has been used in corn breeding programs in the USA (Brown, 1975).

Breeding procedures were used to improve and develop new strains of the open-pollinated cultivars in the late 1800s and early 1900s before the development of inbred lines for hybrid seed production was begun. These breeding procedures included varietal hybridization, mass selection, and ear-to-row selection. Descriptions of the procedures have been published in earlier years, and results from a few studies were summarized by Sprague and Eberhart (1977). These procedures were not successful to effect yield improvements. In some instances, varietal hybridization

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gave crosses that produced better than the higher-yielding parent, but the procedure was not accepted widely for commercial use. Selection programs were successful in producing numerous strains that varied for maturity, plant type, ear and grain type, and pest resistance. Corn shows conducted at the start of the 20th century also caused selection for a distinct ear and grain appearance. Close selection to type, however, may have caused some inbreeding, which may have been the primary reason that yield improvements were not realized. Mass selection and ear-to-row breeding were gradually discontinued as inbred development for hybrid use became the accepted method. Modifications to mass selection (Gardner, 1961) and ear-to-row selection (Lonnquist, 1964) recently have been used to enhance the effectiveness of these selection methods for improving yield in breeding populations.

Results of breeding studies by Shull, East, and Jones in the early 1900s led to the establishment of programs at many U.S. agricultural experiment stations and by the USDA for the development and evaluation of inbred lines and hybrids during the period of 1915 to 1925. Corn breeding as a private commercial enterprise came a few years later. It was the 1930s before farmer use of hybrid seed became an acceptable practice; hybrid corn occupied approximately 100% of the corn area in Iowa by 1943, 90% of the corn area in the U.S. Corn Belt, but only 60% of the corn area for the entire USA (Fig. 8-1). Double-cross hybrids were the predominant type in the USA until about 1960 when the use of single crosses began to increase. Single crosses became the predominant type in a few years, with considerably fewer hectares being planted to related-line single crosses, three-way crosses, and double crosses.

Corn breeding for the development of inbred lines and hybrids in other parts of the world expanded rapidly after World War II. Corn has proved to be a flexible species amenable to selection such that progress

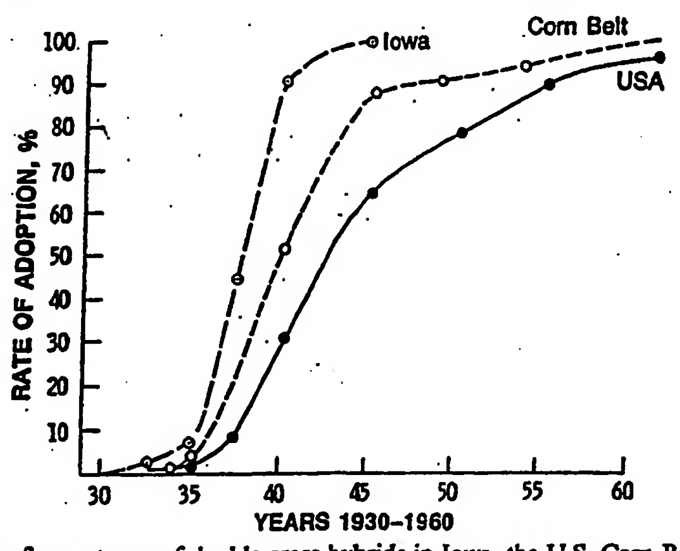

Fig. 8-1. Rate of acceptance of double-cross hybrids in Iowa, the U.S. Corn Belt, and the USA.

has been achieved to develop types adapted to many areas where it was not grown or was relatively unimportant in earlier years. An excellent example has been the tremendous expansion in some European countries, made possible by the selection of earlier maturity, better adapted cultivars that can be grown successfully in areas where such was not feasible 40 years ago (Trifunovic, 1978). Some inbred development and evaluation were done in a few European countries before 1940, and such programs were expanded greatly after 1945. In the first period of this expansion, materials from the USA were evaluated and some U.S. hybrids were used. Subsequently, European and U.S. lines in hybrid combinations were developed and these helped to expand the corn-growing area and to give higher yields. The European lines introduced greater cold tolerance and adaptation for earlier maturity and the U.S. lines added improved yield and standability. These combinations permitted the expansion of hybrid corn into central Europe. In France, for example, the hectarage has increased more than five times from pre-World War II to the present time, and France is now a leading corn producer in Europe. Corn has become the most important feed crop in southern and central Europe.

Corn ranks second to wheat in total production among the world's cereal crops (CIMMYT, 1984). World corn production now normally exceeds 400 million t. During the period 1970–72 to 1981–83, world corn production increased about 120 million t, which represents a 42% increase in the world supplies at a rate of 3.1% yr^{-1}. More than 50% of the total world area planted with corn is in Latin America, Africa, and south and southwest Asia, but probably <25% of the total grain production is in this area (Wellhausen, 1978). Hybrids are the primary type grown in Argentina, South Africa, and parts of Brazil, but the remainder of the area uses open-pollinated cultivars, improved synthetics, variety crosses, and hybrids. In some areas where corn grain is used primarily for human consumption, considerable work has been done to improve protein quality through the use of *opaque-2*. As the technology is improved, it seems likely that hybrid types will become more important in most of the tropical and subtropical areas.

Corn grain yields in the USA have increased from approximately 1.3 Mg ha^{-1} in 1930 to 7.5 Mg ha^{-1} in 1985 (Fig. 8–2). Before 1930, average yields were static because no yield gains were realized from breeding and essentially no improvement occurred because of changes in cultural practices. The mass and ear-to-row selection methods that breeders and seedsmen used before 1930 were not effective in yield improvement. Yield increases have occurred since mid-1930s because of the use of hybrids, increased use of fertilizers, better weed control, higher plant densities, and improved management. The rate of yield gain increased beginning about 1960 when single-cross hybrids gradually replaced double crosses. Also, there was a rapid increase in the use of N fertilizer during 1960 to 1970 (Thompson, 1986). Mean yields plotted in Fig. 8–2 show a greater variability among years for average yields in the 1970s, but there is no

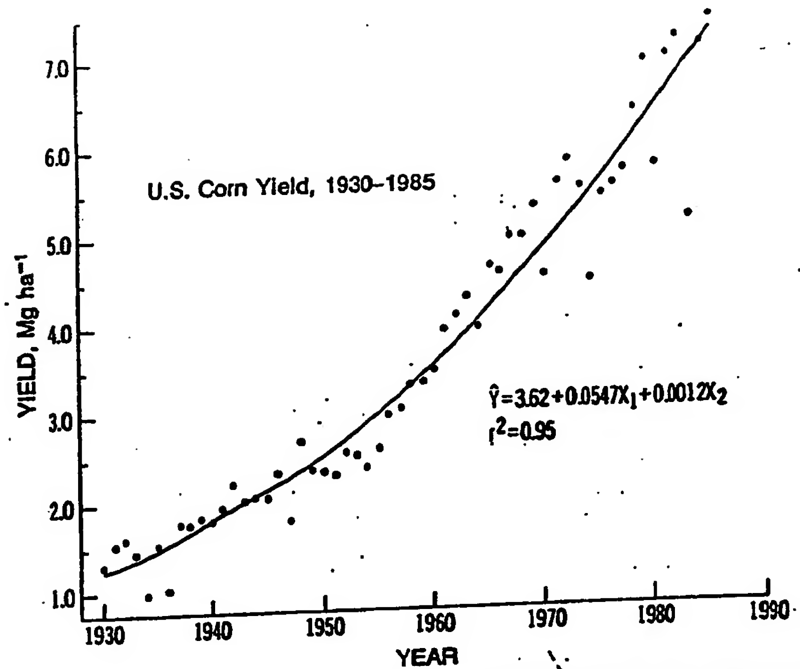

Fig. 8–2. National average of corn yields in the USA for the period including 1930–1986.

evidence of a plateau effect. Thompson (1975), by using a regression equation derived from corn yields and weather data in Illinois, predicted yields in that state would level off at 7.5 Mg ha^{-1} by 1985.

Evidence for the contribution of breeding to corn yield increases has been obtained in several experiments (Russell, 1974, 1984, 1985a, 1986; Duvick, 1977, 1984; Crosbie, 1982; Tapper, 1983; Castleberry et al., 1984; Meghji et al., 1984). Most of these experiments included hybrids that were representative of materials grown from 1930s to 1970 or 1980; in a few studies open-pollinated cultivars from prehybrid times were included. Frey (1971) and Darrah (unpublished data reported by Hallauer, 1973) obtained estimates by using data from the Iowa Corn Yield Tests; all other data were obtained in experiments designed purposely to obtain information to assess genetic gains. A summary that includes total and genetic gains is given in Table 8–1. Total gains ranged from 0.078 to 0.110 Mg ha^{-1}yr^{-1} and genetic gains were 0.033 to 0.092 Mg ha^{-1}yr^{-1}. The estimates, using open-pollinated cultivars as the basis for the proportion of total gain that was caused by genetic improvement, ranged from 56 to 89% for the planned experiments; some may be considered actual genetic gains whereas other estimates were biased because of harvest method. For example, the estimates of machine-harvested plots (see footnotes, Table 8–1) are likely biased in favor of newer hybrids because greater stalk lodging of the older hybrids would be expected to have caused greater harvest losses. The combined effects of improved cultural practices and better hybrids were confounded in these experiments. The hybrids have increased in yield because of their continued improvement in genetic potential to take advantage of improved cultural practices.

Table 8-1. Summary of 13 estimates of total grain yield gain and the genetic total yield gain of corn hybrids. (Table 3 from Russell, 1986). Adapted from Duvick (1984).†

Author	Year reported	Time span	Experiment yr	Total gain	Genetic gain	
				— Mg ha^{-1} yr^{-1} —		%
Frey	1971	1926–1968	1926–1968	–	–	56
Darrah	1973	1930–1970	1930–1970	0.099	0.033	33
Russell	1974	1930–1970	1971–1973	0.078	0.063	79
Russell‡	1974	1930–1970	1971–1973	0.078	0.049	63
Duvick	1977	1935–1971	1972–1973	0.088	0.050	57
Duvick	1977	1935–1972	1972–1973	0.088	0.053	60
Tapper§	1983	1930–1970	1980–1981	–	–	42
Tapper§	1983	1930–1970	1980–1981	–	–	67
Castleberry et al.	1984	1930–1980	1980–1981	0.110	0.082	75
Duvick	1984	1930–1980	1978–1980	0.103	0.092	89
Duvick	1984	1930–1980	1977–1979	0.103	0.073	71
Russell	1984	1930–1980	1981–1982	0.090	0.071	79
Russell‡	1984	1930–1980	1981–1982	0.090	0.050	56

† Gains calculated basis U.S. corn yields by Castleberry et al. (1984); basis Iowa state yields for all other estimates.
‡ Adjustments made to estimate gains because of difference between experiment and Iowa state average yields.
§ Gains calculated relative to 1930-era hybrids; first estimate—total yields, second estimate—machine harvest yields.

The newer hybrids, 1970 or 1980, compared with hybrids of the 1930s had higher yields at all plant densities, and the differences generally were greater at higher plant densities. The newer hybrids had the genetic potential to take advantage of the higher number of plants per unit field area and, thus, to produce much higher yields than the older hybrids. The older hybrids generally had more barrenness at the higher plant densities than did the newer hybrids. Also, differences between the older and newer hybrids for lodging increased with higher plant densities, with the newer hybrids showing considerable superiority.

Castleberry et al. (1984) compared cultivars from six decades, 1930 to 1980, in low- and high-fertility conditions at one location for 2 yr. The high-fertility area had received normal fertilizer applications for 20 yr, whereas the low-fertility area had been in continuous corn and unfertilized since 1958. The higher fertility area received approximately 200 kg of N ha^{-1}, 90 kg of P_2O_5 ha^{-1}, and 150 kg of K_2O ha^{-1} in 2 yr of test; the low-fertility area received no fertilizer. The yield response relative to decades of cultivars was 0.087 Mg ha^{-1}yr^{-1} in the high-fertility condition and 0.051 Mg ha^{-1}yr^{-1} in the low-fertility condition. The newer hybrids were superior to the older cultivars in both fertility levels, and the superiority was greater for the high-fertility area than for the low-fertility area.

Duvick (1984) evaluated four single crosses representative of four decades, 1940 to 1970, at low, intermediate, and high N levels. His newer

four cultivars from each of seven eras (pre-1930–1980) and evaluated them in 12 treatment combinations of three plant densities and four N levels. Grain yields showed that the treatments (plant densities and N levels) were interdependent, and the interaction of the two treatments varied among cultivars; i.e., the densities × N levels × cultivars interaction was statistically significant. The newer cultivars, 1970 and 1980 eras, were the highest yielding at all N levels, and each cultivar seemed to have a unique plant density-N level combination at which it produced a maximum yield. Differences among eras for N response showed no distinct patterns relative to the eras.

Improvement for resistance to root and stalk lodging, which was necessary to permit machine harvesting and the use of higher plant densities, was achieved. Selection for disease resistance has been an integral part of corn breeding for many years, yet there are little data that reflect directly on the effect of greater resistance to grain yield. Improvement for stay-green, which is primarily a visual rating for plant health, has been well documented (Duvick, 1984; Tapper, 1983; Meghji et al., 1984; Russell, 1985a), and stalk quality is dependent upon total plant health. Stay-green may also reflect improvement for resistance or tolerance to second-generation European corn borer [*Ostrinia nubilalis* (Hübner)]. Duvick (1984) showed a continuous improvement in the resistance to second-generation European corn borer from the 1930 to the 1980 hybrids, which would be conducive to greater stalk quality and reduced harvest losses.

The commercial use of single-cross hybrids has been made feasible by improvement of parental inbred lines. Agronomic improvements include cold tolerance such that germination and emergence are better, resistance to plant diseases and insects, resistance to barrenness, resistance to lodging, better pollen production, higher seed yield, and better seed quality. Duvick (1984) found that 1970 inbreds compared with 1930 inbreds had a yield gain of 0.05 Mg $ha^{-1}yr^{-1}$, or a total predicted gain of 2.0 Mg ha^{-1}. Meghji et al. (1984) obtained no yield increase for 1950- compared with 1930-era inbreds, but the 1970-era inbreds had an average yield increase of 14.5% over the 1950 lines. Furthermore, the 1950- and 1970-era inbreds were improved for plant health and resistance to lodging compared with the 1930 inbreds. Whereas in earlier years breeders selected lines primarily on the basis of hybrid performance, now more emphasis is given to the development of lines that have greater vigor and, thus, higher seed yields.

Yield increases in other corn-growing countries began later than in the USA partly because improved cultivars, including hybrids, were not generally used until after World War II. For Europe, the estimated yield increase per hectare was 2.4-fold for 1969 to 1973 over 1934 to 1938 (Trifunovic, 1978). In France, the yield increase per hectare was 3.2-fold for the same period. These increases occurred because of both improved cultivars and better field husbandry. Wellhausen (1978) reported that a

double-cross hybrid released in Brazil in 1958 yielded approximately 50 and 58% better than 'Paulista' and 'Cateto', respectively, the two most common races grown in Brazil in earlier years. Kuhn and Gevers (1980) found for 2 yr, in South Africa 1977/78 and 1978/79, that the best hybrids yielded 41.2% above the mean for the first hybrids released. Most of the increase in world corn production was achieved by yield improvement. In developing countries, yields increased 2.6% yr^{-1} while the area planted increased 1% yr^{-1} (CIMMYT, 1984).

Further increases in corn yields are expected primarily because of the combined effects of two factors: (i) improved cultural practices and management and (ii) increased genetic potential of the hybrids. The rate of genetic gain for grain yield could become even greater than shown previously because there are now more breeders and companies with breeding programs. It seems likely further gains will be achieved by the development and evaluation of parental materials at higher plant densities. Stalk lodging will be a problem and must be corrected if higher plant densities are to be used. Recurrent selection can be used effectively to improve stalk quality in breeding populations, but must be done with yield evaluation to avoid yield declines (Devey and Russell, 1983; Martin and Russell, 1984a, b). Genetic engineering techniques have not yet had an impact on corn improvement, but effects for some aspects of corn improvement may be realized in the near future. Also, we have only just begun to explore in greater depth the possible utilization of germ plasm from other areas.

8–1 BREEDING METHODS

8–1.1 Methods for Line Development

The essential features of the inbred-hybrid concept used in corn breeding were eloquently described by Shull (1908, 1909, 1910). The major focus of corn breeding programs is the same as that stated by Shull (1909) "... the object of the corn breeder should not be to find the best pure line, but to find and maintain the best hybrid combination." Shull's suggestion was not immediately accepted because of the practical concerns of producing adequate quantities of hybrid seed at an acceptable cost. These concerns were alleviated with Jones' (1918) suggestion that single crosses be used as parents to produce double crosses rather than inbred lines used to produce single crosses, as suggested by Shull (1909). Hence, the basis for producing and growing hybrid corn was in place by 1920. During the 1920s, the USDA, state agriculture experiment stations, and individuals initiated corn breeding programs to develop and test inbred lines and hybrids. Agencies and individuals responded to Shull's

(1910) plea that, "My anxiety is not for success of the pure-line methods outlined by myself, but that serious experimentation shall be undertaken by every station within the corn-growing region for the purpose of discovering what is the best method."

8–1.1.1 Pedigree Selection

Pedigree selection is the most widely used breeding method to develop inbred lines for use as parents of hybrids. The types of populations sampled, methods of selection used, and the emphasis given to traits during selection have changed, but the basic principles of pure-line development are used. Initially, pedigree selection was practiced in the open-pollinated landrace cultivars that were adapted to the areas in which the breeding programs were located. Useful inbred lines (e.g., L317, L289, I205, Os420, WF9, etc.) were developed from the landrace cultivars, but it soon became obvious that repeated samplings of the same landrace cultivars were not productive. A logical sequel was to cross pairs of elite inbred lines that complemented one another, produce the F_2 generation, and practice pedigree selection by sampling the F_2 population. F_2 populations of single crosses are the most frequently (37%) used source populations for line development (Bauman, 1981). Other populations frequently used by U.S. breeders to initiate pedigree selection include genetically broad- (15%) and narrow-base (16%) populations improved by selection for specific traits, and populations (14%) formed by intermating elite inbreds that may be either related or unrelated (Bauman, 1981). The choice of germ plasm depends on the breeding objectives, stage of development of breeding program, and germ plasm available.

The scheme of the pedigree selection program depends on the skills of the individual breeder, primary breeding goals, the resources available for advancing the progenies, intensity of selection, and scope of testing. Different breeders emphasize selection for different traits because of locally important pests at different stages of inbreeding. The intensity of selection will vary, depending on the effective screens available for pests, environments available, and types of material under selection. One common feature, however, is that records are kept for each progeny for the traits selected for each generation of inbreeding.

Adequate sample sizes of the source breeding populations are necessary to include the range of possible segregants. In most instances, however, it is not possible to have a sample size that includes the theoretical number of possible genotypes for the segregating loci. If, for example, the cross between two parents differed for five allelic pairs, the smallest theoretical F_2 population would require 1024 individuals; if the parents differed for 10 allelic pairs, the theoretical F_2 populations would include 1 048 576 individuals. Most of the traits emphasized in selection of lines are controlled by more than five genetic factors, and, therefore, compromises are made for sample sizes because the breeder usually is sampling more than one population. Generally, the decision on sample

size depends on the heritability of the trait to be improved and(or) the experience of the breeder making the selections among progenies. Bauman (1981) reported there was great variation among the initial sample sizes, with sample size of 500 being the more common. After the initial sampling, the number of progenies surviving in subsequent generations of inbreeding (without testcross evaluation) was quickly reduced. The idealized number of surviving progenies after sampling 500 plants (S_1 progenies) was reported by Bauman (1981) to be 180 in the S_2 generation, 80 in the S_3 generation, and 40 in the S_4 generation. Average selection intensities were 63, 56, and 50% in the S_1, S_2, and S_3 generations, respectively, for visually selected traits. The breeders preferred use of smaller sample size in a greater number of populations rather than greater sample size in one or two populations.

The general procedure with use of F_2 populations is to initiate selection and selfing without any genetic recombination. The breeder usually has a mental image of the ideotype desired, and, depending on the skill of the breeder, desirable ideotypes of the favorable parent can be recovered with slight modifications. Favorable linkages would be desirable in these instances. The effects of random mating within F_2 populations before sampling are not conclusive. Pederson (1974) and Bos (1977) have presented theoretical arguments against random mating in F_2 populations of self-pollinating species. Altman and Busch (1984) reported there was insufficient useful recombination to justify random mating single-cross populations of wheat (*Triticum aestivum* L.) before initiating selection. Humphrey et al. (1969) in tobacco (*Nicotiana tobacum* L.) and Nordquist et al. (1973) in sorghum [*Sorghum bicolor* (L.) Moench] reported random mating increased genetic recombination which provided desirable recombinants.

Empirical data for random mating single crosses of corn before conducting pedigree selection are limited. Covarrubias-Prieto (1987) estimated the variability among 100 S_1 progenies in F_2 populations of B73 × Mo17 (cross of unrelated lines) and B73 × B84 (cross of related lines) and after five generations of random mating 250 plants in each F_2 population. Objectives of the study were to determine if random mating was effective for increasing genetic variability in populations formed from single crosses and if the relatedness of the inbred lines used to make the cross was an important consideration for random mating. Preliminary evidence suggests that random mating did not increase genetic variability in either F_2 population. Estimates of the S_1 components of variance were similar for the F_2 and F_2 random mated six times. Indirect evidence suggests that selection and intermating are effective via use of recurrent selection procedures (e.g., B14, B37, B73, and B84 derived by pedigree selection from cycles of selection in BS13).

Pedigree selection will always be an important component of modern corn-breeding programs. Based on surveys by Hallauer (1979) and Bauman (1981), it seems pedigree selection will be emphasized in populations

with a restricted genetic base. Because of the availability of elite lines and competition among private companies to provide high-performance hybrids, germplasm sources that include favorable linkages will be used to increase the odds of recovering elite lines and hybrids. The skills of the breeder in selection and the precision of testing have been found effective for developing improved lines and hybrids by pedigree selection (Duvick, 1977; Bauman, 1977). Except for germplasm sources, the methods of selection and hybrids currently produced and grown are those described by Shull (1909, 1910).

8-1.1.2 Backcrossing

Backcross method of breeding is a modification of the pedigree method and is an important component of most breeding programs. Bauman (1981) reported that 17% of the total effort for inbred line development was allocated to backcross sources. The main difference between backcross and pedigree selection is in the objective of the crosses and the level of recovery of the recurrent parental genotype. The complexity of the backcross method depends on type of trait being transferred (single gene vs. several genes), level of expressivity, whether cytoplasmic or nuclear inheritance, and the types of parents included in the crosses. For single gene traits that are relatively easy to classify, the backcross method is effective and relatively easy to manage. For traits that have a more complex inheritance, the backcross method requires greater selection pressure for the desired trait, but it has been successfully used to transfer traits in which the effects of individual genes were not known (e.g., Duvick, 1974).

Modifications of the backcross method have been suggested. Convergent improvement was a concept developed by Richey (1927) for the parallel improvement of two inbred lines by the reciprocal addition of dominant favorable genes present in one line but lacking in the other line. Richey and Sprague (1931) and Murphy (1942) presented experimental evidence that convergent improvement was effective for yield improvements of the recovered lines and their respective single crosses. However, convergent improvement is apparently not an important component of current breeding programs.

For traits that have a more complex inheritance, usually some modifications are needed to transfer the trait effectively. Bailey (1977) and Johnson (1980) presented formulae and examples of the probabilities of recovering more than "n" loci with "x" favorable alleles. Their theoretical calculations, based on F_2 populations where $p = q = 0.5$ for segregating loci, support the experiences in breeding. If the trait being transferred has a high heritability (nearly 100%) for a trait, such as *Ht* conditioning resistance to *Helminthosporium turcicum* Pass. (Hooker, 1961), the chances of recovering the favorable alleles of the recurrent parent are good with successive backcrosses. Tight linkages of unfavorable alleles with the gene being transferred from the donor parent would, of course, affect the outcome in an obvious manner (Bailey and Comstock, 1976).

If the trait is conditioned by 20 genes, has a heritability of 0.50, and a 10% selection intensity is used, Bailey (1977) showed that the probability of obtaining a recovery with 80% of the favorable alleles was 0.271 in the second backcross. The greater the number of loci, the lower the probabilities in recovering all of the favorable alleles. Johnson (1980) concluded that, the more divergent the parents in making the crosses, several backcrosses to the better parent will be required to enhance the probability of obtaining a recovery superior to the better parent.

8-1.1.3 Gamete Selection

Gamete selection is a scheme devised by Stadler (1944) for sampling elite gametes from a population. Stadler's premise was that, if superior zygotes occur with a frequency of p^2, the superior gametes would occur with a frequency of p. The procedure involves crossing an elite line with a random sample of pollen of plants from a source population; each of the F_1 plants and the elite line are testcrossed to a common tester and the F_1 plants are also selfed; testcrosses are evaluated in replicated trials; and the testcrosses of F_1 plants that exceed the elite line by tester are presumed to have obtained a superior gamete from the source population. Experiments testing the effectiveness of gamete selection reported by Pinnell et al. (1952), Lonnquist and McGill (1954), El-Hifny et al. (1969), and Burton (1982) suggested superior lines could be recovered from the use of gamete selection. But Giesbrecht (1964) reported the method was not effective. It should be emphasized, however, that it is not possible to recover the superior gamete itself because the F_1 plants were self-fertilized; this has been the primary criticism of the purported advantage of the gamete selection scheme (Richey, 1947). The disadvantage of the original concept of gamete selection can be alleviated if individual plants from the source population are crossed to the elite line and also self-fertilized, in which case superior genotypes rather than superior gametes are selected (Hallauer, 1970). Though gamete selection is not used as extensively as pedigree and backcross methods, it does have some intrinsic features that interest breeders, and, consequently, gamete selection is included in some breeding programs.

8-1.1.4 Special Techniques

Several suggestions have been made for the instantaneous derivation of homozygous inbred lines. These techniques have involved the doubling of haploids derived from either maternal or paternal gametes (Chase, 1952; Goodsell, 1961; Kermicle, 1969). Genetic markers were used to identify haploids, and the haploids were doubled to form homozygous diploid inbred lines. The disadvantages of the methods were the low frequency of the occurrence of haploids and doubling of haploids to the diploid state. Kermicle (1969) reported on a spontaneous mutant (*ig*) that increased the frequency of occurrence of haploids (about 3%). Advantages of the use of haploids were the rapid production of new inbred lines and

use in the conversion of inbred lines from normal to sterile cytoplasms. Each of the methods has been used and tested, but it does not seem they are important components of most breeding programs. Although the methods are capable of rapid development of homozygous inbred lines, they would represent a random sample of genotypes that would require the standard methods of evaluation (Thompson, 1954).

Somaclonal variation within inbred lines submitted to tissue culture has been reported (Edallo et al., 1981; McCoy and Phillips, 1982; Earle and Gracen, 1985; Lee et al., 1988). Hence, it seems genetic variation can be derived within inbred lines for selection without making crosses between lines to create genetic variability. Most of the variation observed phenotypically is due to single genes; e.g., albinos. If, however, genetic variation for traits conditioned by 20 or more genes approaches a normal density distribution, tissue culture may permit the recovery of second-cycle lines that include the original genome that also include a gene(s) for other traits; e.g., resistance to a specific herbicide. Tissue culture would have the advantage over other breeding methods for creating variation within an inbred line. The disadvantages, however, would be the same as for the other standard breeding methods: restriction of germ plasm and the probabilities of recovering all the favorable genes of the original line may be low. The genetic changes seem to occur randomly, and, consequently, it would be necessary to evaluate the derived materials similar to other breeding methods (Lee et al., 1988). Somaclonal variation is a recent source of genetic variability that may have an important role in breeding programs. But pedigree and(or) backcross breeding methods will be used to determine its future use.

8-1.1.5 General

After the initial sampling of the landrace cultivars, breeding methods that emphasized inbred line modification have been widely used. A few inbred lines (e.g., B14, B37, C103, and Oh43) possessed traits considered important as lines themselves and in crosses with other elite lines. The lines were included in pedigree and backcrossing breeding programs to modify certain traits (e.g., earlier flowering strains of A632 and CM105 with B14 background and of A619 with Oh43 background), improved pest resistance (e.g., improved first-generation European corn borer resistant strains of B64 and B68 with B14 background and of B76 with B37 background), and improved ear shoot emergence (e.g., Mo17 with C103 background and B76 with B37 background). Because of the nature of the traits under selection, combinations of pedigree and backcross methods sometimes were used to attain the level of expression needed for effective selection. Development of lines B64 and B68 is an example. Both lines were derived from an initial cross of B14 and Amargo 41.2504B made in 1950. B14 was susceptible to first-generation European corn borer leaf feeding, whereas Amargo 41.2504B, an introduction from Argentina,

had first-generation, leaf-feeding resistance. The objective of the cross was to increase the level of resistance to first-generation European corn borer leaf feeding in B14. Two backcrosses were made to B14 to recover the B14 genotype, but with selection for leaf-feeding resistance under artificial infestation. B64 was developed from the second backcross generation (Amargo 41.2504B × $B14^3$) with the use of standard pedigree selection methods and released in 1964. The level of resistance relative to Amargo 41.2504B, however, decreased with backcrosses to B14. Selfed progenies from the second backcross were artificially infested with corn borer egg masses. Progenies that exhibited higher levels of resistance to leaf feeding were intermated. Selected progenies from the first intermated generation also were infested, rated, and intermated to form the second generation of intermating. Pedigree selection was initiated in the second intermated generation and B68 was released in 1966. Although B64 and B68 were derived from the same backcross generation, the differences in breeding methods used (standard pedigree selection for B64 and intermating, selfing, intermating, and seven generations of selfing for B68) isolated lines with differences large enough to justify release. In addition to the breeding methods used for developing B64 and B68, the source of germplasm also has been a contributing factor in their use (Zuber and Darrah, 1980). Because B64 and B68 also possessed tolerance to corn lethal necrosis, which is caused by a combination of maize dwarf mosaic virus (strain B) and maize chlorotic mottle virus (Doupnik et al., 1981), Amargo 41.2504B also seems to have contributed genes for tolerance to corn lethal necrosis.

The conversion of late-maturity lines to earlier derivatives is another illustration of the effective combination of breeding methods to develop second-cycle lines that have earlier maturity. The methods used to develop earlier maturity derivatives depend on the inbred line being converted and the source of earlier maturity. B14 has acceptable stalk strength, good pest tolerance, rapid grain dry-down, and good combining ability for the central U.S. Corn Belt. Because of these favorable traits, it was considered desirable to obtain earlier maturity second-cycle recoveries of B14 for use at higher latitudes. Earlier maturity recoveries have been obtained, but the breeding methods used have varied. In most instances, early-by-late crosses are produced with subsequent selection for the late phenotype that has earlier maturity. Rinke and Sentz (1961) outlined the breeding methods used in Minnesota. Their program was successful for developing earlier maturity recoveries of genotypes that have been widely used in commercial hybrids (Table 8–2). A632 and A634 were obtained from a cross of Mt42 × B14. A632 was extracted by pedigree selection after the third backcross to B14. A634 also included three backcrosses to B14, but there was one generation of selfing after the first backcross; there were two additional backcrosses made to B14 after one generation of selfing. A635, A640, and A641 were selected from a cross of ND203 × B14; A635 was selected after two backcrosses to B14, whereas A640 and

Table 8–2. Breeding methods used in the development of earlier maturity lines from early × late crosses. Adapted from Rinke and Sentz (1961).

Breeding method after cross No. of generations: Backcrosses to late parent	Self-fertilization	Frequency of late parent	Example of method
	no.		
4	3	5	A671
3	4	4	A632, A634
2	5	3	A635
1	6	2	A619, CM105†
0	7	1	A640, A641

† CM105 developed by John Giesbrecht (1974, personal communication).

A641 were pedigree selected directly from the F_2 generation. Although Mt42 and ND203 have similar flowering dates (about 85 d), selection for earlier flowering progenies with genotypes similar to B14 must have been easier in crosses to ND203 than to Mt42. In a separate program, CM105 was developed by pedigree selection in the first backcross generation of the cross, CMV3 × B14 (J. Giesbrecht, 1974, personal communication). Hence, earlier derivatives of B14 were obtained after three (A632 and A632), two (A635), one (CM105), or zero (A640 and A641) backcrosses followed by pedigree selection. The combination of breeding methods depends on the heritability of the trait, expressivity of the trait from the nonrecurrent parent in the cross, and the extent one wishes to recover the phenotype of the recurrent parent. Table 8–3 illustrates briefly some of the methods suggested for managing late × early crosses. Similar methods could be used for other traits.

The traditional pedigree selection methods of corn breeding obviously have been effective (Duvick, 1977; Russell, 1974, 1984, 1986). But there has been concern that the genetic base of the germ plasm included in breeding programs has become restricted to a few elite genotypes (Anonymous, 1972, p. 97–118). Jenkins (1978) emphasized that the intercrossing of elite lines and reselection to develop second-cycle lines gradually limits the genetic base of the breeding germ plasm. Second-cycle lines have become the main component of present-day breeding programs, at least for lines released by public agencies. Jenkins (1936) listed 350 lines released by public agencies of which only eight (2%) were second-cycle lines. The trend has increased in subsequent decades, and it is estimated that by 1976 76% of the lines released by public agencies were second-cycle lines. The same trends seem to have occurred in the private sector (Smith, 1988).

Some of the limitations of the pedigree method of breeding were suggested by Bailey and Comstock (1976) and Bailey (1977) in simulation studies. They studied intra-line selection within an F_2 population developed from a pair of inbred lines followed by selection among pure lines.

Table 8-3. Breeding selection methods suggested and used for developing early lines from early by late crosses.

Season	Rinke and Sentz (1961)	Baker†	Troyer†
1	Early × late cross	Early × late cross	Balanced set early × late crosses
2	Produce F_2 500 plants	Produce F_2	Yield test for GCA and SCA. Produce F_2
3	Backcross (BC) earliest F_2 to late parent	Self earliest F_2 plants	Self earliest 5 to 10% F_2 plants
4	Grow 15 BC ear-to-row with 100 plants per progeny. Self or BC 10 early plants in 3 early progeny rows	Self earliest plants in early progenies with late parent phenotype	Sib or BC earliest plants to late parent
5	BC or self BC. Select earliest plants in early progeny rows in each generation.	Self earliest plants in early progenies with late parent phenotype	Grow 800 plants and self or BC to late parent the earliest 5 to 10%
6	BC or self BC. Select earliest plants in early progeny rows in each generation.	Self earliest plants in early progenies with late parent phenotype	Grow 800 plants and self or BC to late parent the earliest 5 to 10%
7	BC or self BC. Select earliest plants in early progeny rows in each generation.	Yield test for GCA	Repeat BC or begin pedigree selection
8	Yield test topcrosses	Backcross best to late parent	Repeat BC or begin pedigree selection
9	Make selections	Backcross best to late parent	Repeat BC or being pedigree selection
10	Make selections	Backcross best to late parent	Repeat BC or being pedigree selection

† Raymond Baker and A.F. Troyer (1982, personal communication).

The objective of their studies was to determine the relative probabilities of accumulating in one derived progeny all of the favorable alleles present in either one of inbred lines used to produce the cross. Chances of success, of course, depended on the parents included in the cross. If one parent of a cross is decidedly better than the other parent, as in the case of B14 compared with Amargo 41.2504B, the chances of obtaining a derivative line superior to the better parent are remote. If the two inbred lines included in the cross differ in alleles for a moderate number of loci (e.g., 25 or more), it is unlikely that all of the favorable alleles would be assembled in one line. The other situation examined included two inbred lines that had equal numbers of loci with favorable alleles; e.g., each line included 15 favorable alleles of the 30 loci heterozygous in the F_1. The probability of obtaining a derivative line from this cross that is homozygous for 16 or more favorable alleles is 0.825, and the probability that a derived line is homozygous for 20 or more favorable alleles is 0.292. Johnson (1980) also concluded from a theoretical study that little or no progress could be expected from pedigree selection unless the parents

were nearly equal in value. The theoretical simulation studies support the general observation that selection is more productive within populations developed from crosses of good lines × good lines than from crosses of good lines × poor lines. The latter situation is reserved primarily for transferring specific traits that are not available from crosses of good lines.

Although Jenkins (1978) suggested more attention should be devoted to broadening the genetic base of new breeding germ plasm, practical considerations often limit a breeder's choice of germ plasm. New alleles can be introduced from other sources, but new sources usually do not meet the performance standards of the elite germ plasm currently available. The chances of obtaining lines that exceed the currently available well-evaluated inbred lines are not good. Hence, the tendency is to continue to recycle elite inbred lines that have demonstrated performance in hybrids. Other sources of germ plasm will not be used until they have been developed to be competitive with current germplasm sources.

8–1.2 Developing Inbred Lines

The development of inbred lines by self pollination and the evaluation for hybrid performance is the basic procedure in corn breeding programs of the U.S. Corn Belt and in many other areas where corn breeding is done. Information from research and experience has increased effectiveness of breeding procedures compared to earlier years. Breeders continue to search for better methods that will be more effective in the development and identification of inbred lines that have the genetic potential to contribute superior agronomic performance to hybrids. The breeder seeks the procedure that permits the greatest genetic gain per unit of resource input.

Most applied breeders seem to use similar procedures, with minor variations such as plant densities, number of plants per progeny row, number of self pollinations per row, generation at which to start hybrid testing, etc. Probably there is considerable similarity of germplasm sources used by breeders in different programs. Most breeders use an ear-to-row system with inbreeding and selection for several generations until a line is highly homozygous and homogeneous. Some breeders may use only two or three generations of self pollination with subsequent reproduction by sibmating within progenies. This latter procedure will produce somewhat more vigorous lines that yield more seed and produce more pollen than highly inbred lines, but genetic stability may be a problem. Although the single-seed descent procedure used by breeders of self-pollinated crops is used by few corn breeders, there may be a use for it (Brim, 1966). For example, in winter nurseries where the cost per unit land area is high, single-seed descent may be useful to advance a generation for a large number of lines at the S_1 or S_2 level of inbreeding.

One system of inbred-line development relies on phenotypic selection

among and within ear-to-row progenies for several selfing generations before evaluation for hybrid performance. Selection is performed to isolate lines with resistance to important pests, maturity for certain areas of adaptation, plant canopy type, ear size, and grain quality. These traits have reasonably high heritability estimates and are deemed necessary for hybrid performance. For the first progenies of self pollination, S_1 lines, the additive genetic variance among lines is σ^2_A, and this becomes $2\sigma^2_A$ when $F = 1$. The within-line genetic variance is maximum in the S_1 generation, but decreases rapidly with self pollination and is zero when $F = 1$. Consequently, phenotypic differences among lines increase with continued self pollination in ear-to-row progenies, but success of selection within a line becomes reduced usually by the S_3 and later generations. Therefore, selection effort should be directed primarily to among progenies and less within progenies as inbreeding continues. Testing for hybrid performance may be delayed to about the fifth generation of selfing when the number of selections should be greatly reduced. This breeding system assumes favorable relationships of plant, grain, and ear traits of inbred lines with combining ability for grain yield; thus, the selected lines should be better for hybrid performance than would a random set of lines from the same source (Jenkins, 1935; Sprague, 1946).

A second system of inbred development is based on an evaluation for hybrid performance in the early generations of self pollination; e.g., testcrosses of the S_0 plants or S_1 lines. Genotypes that are identified for above-average hybrid performance in these tests are continued in the selfing and selection nursery. The procedure has been called "early testing," and the assumption is that the combining ability of a line is determined early in its development and will change relatively little in subsequent generations of inbreeding and selection. By early testing, the breeder is able to discard some portion of lines that are inadequate in hybrid performance, thus expending resources on materials that have more promise. Jenkins (1935) proposed the early testing procedure; Sprague (1946), Lonnquist (1950), Russell and Teich (1967), Hallauer and Lopez-Perez (1979), Johnson (1980), and Landi et al. (1983) presented data that support it. Russell and Teich (1967) also found that visual selection of inbred lines in a high plant density was just as effective as the early testing procedure in the identification of lines with above-average hybrid yield performance. The original objective of early testing seems valid because the only purpose is to identify those lines that are relatively good or poor and to emphasize selection for those that have above-average combining ability. Proponents do not claim that one should expect an exact ranking at two different stages of inbreeding.

Probably most breeders use a method that is intermediate between the two systems just described, i.e., first hybrid evaluations are of S_2 or S_3 lines. Bauman (1981) found in his survey that breeders begin evaluations as follows: S_2, 18%; S_3, 33%, S_4, 27%. Consequently, testing for hybrid performance and selfing and selection are being done simulta-

neously. Regardless of the system used, a selected line must be one that can be used profitably in commercial hybrid seed production either as a male or female parent.

Self pollination of individual plants within single-plant progenies grown ear-to-row is the most common procedure used to develop inbred lines. This breeding procedure has two important problems: (i) Vigor of the lines is decreased with inbreeding because of loss of favorable dominant alleles and any heterozygous loci that have overdominant effects. Many lines are so poor in seed yield, pollen production, or some other desired agronomic attribute that they cannot be used in a program to produce single-cross hybrid seed. (ii) Effective selection within the row for plants that have desired agronomic traits becomes minimal in generations beyond S_3; frequently, phenotypic uniformity is evident by the S_2 generation. Once the locus becomes homozygous in a line no further selection for segregating types is possible.

A second system that may be used to develop inbred lines involves some method of sibmating rather than self pollination. Stringfield (1974) has called this a conservative procedure, and he has given a theoretical discussion of the advantages of such a method compared with the development of lines by self pollination. Sib-mating permits the recombination and segregation for loci that have more than one allele in the progeny, thus giving the breeder more opportunity to select for desirable attributes. If sib-mating per progeny involves enough plants, inbreeding will be at a slower rate so that the plants are more vigorous than in a highly inbred line. Such lines would be better for seed yield and pollen production and, therefore, fewer such lines would have to be discarded because they couldn't be used in single-cross hybrid seed production. Sib-mated lines would have some level of genetic heterogeneity; thus, crosses of such lines would have less aesthetic value in hybrid appearance, which seems important to many producers. Greater heterogeneity, however, may give greater stability of field performance. Stangland and Russell (1981) reported that the variability within hybrids of $S_2 \times S_2$ lines was similar to hybrids that have related-line crosses for parents, but less variable than double crosses. Such lines may have gene frequency changes over a period of several generations of maintenance. Because of the heterogeneity of loci it may be more difficult to insert some single genes, as for disease resistance, or to convert to male-sterile cytoplasm by a backcross procedure. Also, it will be more difficult to identify contaminants in lines that are not highly inbred.

An important problem in a conservative program as outlined by Stringfield (1974) is the number of lines that one could develop for evaluation. Considerable time is required to select plants for sib mating at pollination and again at harvest, which means that it is more time-consuming than the standard practice of self pollination. Also, the success is dependent upon the ability of a person to select those plants that have the desired attributes (Mock and Pearce, 1975). Consequently, it is not

a procedure to be used by untrained personnel who do much of the pollination in corn-breeding nurseries.

8-1.3 Correlation of Inbred Traits with Hybrid Performance

Breeders assume favorable correlations between plant, ear, and grain traits of the parental lines and performance in hybrid combination. Several studies have shown that correlation of an inbred trait with the same trait in the hybrid is relatively high, except for yield. Although many *r* values of inbred traits, including yield, with hybrid yield have been positive and significant, in most instances they have been too low to be of predictive value. Consequently, extensive evaluation in hybrid progenies is required to determine the true value of an inbred.

The earlier correlation studies (Jenkins, 1929; Hayes and Johnson, 1939) were done in field husbandry conditions that were at a much lower productivity index than those now used in corn production. The relationship between inbred traits and hybrid performance, however, may be greater in a higher productivity environment with the improved cultivars.

Results from two breeding methods studies (Russell and Teich, 1967; El-Lakany and Russell, 1971) suggested that greater relationships may occur when materials are grown in stress environments, such as high plant densities. Data were presented by Russell and Machado (1978) on inbred lines and correlations of inbred-line traits with hybrid yields when materials were grown at different densities. The source population was BS1 synthetic, which is genetically diverse and adapted to the U.S. Corn Belt. After four generations of phenotypic selection and self pollination, S_1 to S_4, they had 76 S_5 lines. The lines were evaluated in relatively low and high plant densities and testcrosses of the lines (double-cross hybrid tester) were evaluated in low, intermediate, and high plant densities. Although the lines had been selected rigorously for several agronomic traits, there were highly significant differences among the lines for 13 agronomic traits. Also, there were highly significant differences among the lines for testcross yield performance. None of the plant traits in either density of the inbreds had correlations with hybrid yields that were high enough to be of predictive value. Only leaf area showed an important relationship, and it was greater for the lower density than for the higher density of the inbreds, and increased from the highest to the lowest density of the testcrosses. For ear and grain traits, except grain yield, *r* values were slightly greater at the higher inbred density, but changed little from the lowest to the highest density of the testcrosses. For inbred grain yield, *r* values were greater at the higher inbred density, but changed little from the lowest to the highest density of the testcrosses. For example, inbred yields at the low density correlated with testcross yields at low, intermediate, and high densities had *r* values of 0.33, 0.28, and 0.33; for inbreds at the high density and testcross yields at low, intermediate, and

Exhibit 8: Printed pages from the web site of the World Seed Organization

First cited by Applicant in December 14, 2005 Amendment After Final, p. 7. The Amendment After Final was entered by the Examiner in the January 12, 2006 Advisory Action.

ASSINSEL

Essential Derivation and Dependence

Practical Information

WHY THE CONCEPT OF ESSENTIAL DERIVATION?

The 1978 Act of the UPOV Convention (International Union for the Protection of New Varieties of Plants) states that "the authorization by the breeder shall not be required either for the utilization of the [his protected] variety as an initial source of variation for the purpose of creating other varieties or for the marketing of such varieties".

That principle, known as the "breeder's exemption", is essential for continued progress from plant breeding.

However, its implementation has progressively led to some abuses, due to the difficulties involved with assessment of distinctness, based on the text of the Convention (1978) which indicates that, for the basis of a title of protection, "the [new] variety must be clearly distinguishable by one or more important characteristics from any other variety whose existance is a matter of common knowledge ...".

Sometimes, "cosmetic modifications" were enough for protecting a new variety. That was particularly true in the case of mutation of ornamental or fruit plants and of "conversion" by repeated backcrossing of parental lines of hybrid varieties.

In order to improve the situation, in the early 1980's, a debate began on how to improve the system, trying to define "minimum distances" per species, but no consensus was reached. The development of genetic engineering, opened new possibilities for "piracy" of varieties and sped up the revision process of the Convention which, in the Act adopted in 1991, has introduced with the full agreement of breeders' associations, the concept of essential derivation. That concept of essential derivation has two aspects:

- a technical one: the question whether or not a plant variety is to be considered as a variety essentially derived from an initial variety;
- a juridical one: dependence, meaning that no protected acts as defined by the 1991 Act of the UPOV Convention (production, marketing ...) related to the essentially derived variety shall be carried out without the authorization of the owner of the protected initial variety.

DEFINITION OF AN ESSENTIALLY DERIVED VARIETY

The 1991 Act of the UPOV Convention states that "a variety shall be deemed to be essentially derived from another variety (the initial variety) when:

i. it is **predominantly derived** from the initial variety, or from a variety that is itself predominantly derived from the initial variety, while retaining the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial

variety;

ii. it is clearly distinguishable from the initial variety and

iii. except for the differences which result from the act of derivation, it conforms to the initial variety in the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety.

Essentially derived varieties may be obtained, for example, by selection of natural or induced mutants, by selection of a somaclonal variant, by selection of variant individual plants in the initial variety, by backcrossing or by transformation *(genetic engineering)*.

ASSINSEL interprets the definition given in the Convention as follows:

a) **The technical aspects** (matter of facts)

For a variety to be considered as essentially derived, it must fulfil three requirements in relation to the initial variety while retaining the expression of the essential characteristics of the initial variety:

i. clear distinctness in the sense of the UPOV Convention

ii. conformity to the initial variety in the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety

iii. predominant derivation from an initial variety.

If one of these requirements is not fulfilled, there is no essential derivation.

The methods of breeding that can be regarded as leading to an essentially derived variety (see the above-mentioned explanatory list) may differ from species to species or even within a species. This may result in different thresholds being required to characterize essential derivation. Thus, conformity should be judged on a species-by-species or even within a species basis.

b) **The juridical aspect**

The principle of dependence only exists in favour of a protected variety. This means that:

i. the initial variety must be a protected one

ii. dependence can only exist from one protected variety alone

iii. an essentially derived variety can be directly derived from the initial variety or from a variety that is itself predominantly derived from the initial variety. It is possible to have a "cascade" of derivation. However, each essentially derived variety shall only be dependent on one, the protected initial variety. A cascade of dependence shall not exist, the principle having been introduced to better protect the breeder of the initial variety and not those having made derivations from his work.

ASSESSMENT OF ESSENTIAL DERIVATION

The assessment of essential derivation needs to take into account the three criteria mentioned above:

- clear distinctness in the sense of the UPOV Convention
- conformity to the initial variety in the expression of the essential characteristics that result from the genotype or the combination of genotypes of the initial variety
- predominant derivation from an initial variety.

The first criterion will be decided upon by the office in charge of granting a right to the breeder of the variety, according to the UPOV rule of distinctness.

The second criterion could be based on reliable phenotypic characteristics and/or on reliable molecular characteristics: either close relationship in general which could lead to a "conformity threshold" parallel to the minimum distance threshold used for distinctness or only small differences in some simply inherited characteristics. If this second criterion is considered as fulfilled, then, we have to assess the third one, which is "predominant derivation from an initial variety".

The third criterion, predominant derivation from an initial variety, implies that the initial variety or products essentially derived therefrom have been used in the breeding process.

In order to prove that use, various criteria or a combination thereof may be used:

- combining ability
- phenotypic characteristics
- molecular characteristics.

These criteria will have to be handled differently from their use for assessment of distinctness. Whatever solution retained, one will probably have to use distance coefficients to define thresholds. Up to now, ASSINSEL has essentially worked on thresholds based on distances measured by molecular markers. Geneticists and statisticians consider that technically it is equally possible to measure distance coefficients using phenotypic markers. However, the process would probably be more difficult due to environmental factors, and much more expensive: necessity of several testing locations during several years. However, if breeders prefer to use morphological markers instead of molecular markers, that should be possible.

The interest of using combining ability and the heterosis level will strongly depend on the crop. Thresholds will also be necessary.

The various ASSINSEL Sections are considering the establishment of thresholds for characterization of essential derivation according to this following general principle:

- One should propose, species by species, a first threshold below which a variety should be considered as non-essentially derived from an initial variety and a second threshold of conformity above which the new variety should be considered as essentially derived, except if the breeder can prove, by clear evidence, that he has started from independent germplasm.
- Between those two thresholds, the derivation could be disputable and the breeder of the putative essentially derived variety should have to give, in case of amicable negotiation or arbitration, information on the origin of the new variety. Should that information be unsatisfactory, the tribunal or of arbitrators/conciliators agreed on by both parties may request breeding records be provided for their examination.

This approach may be diagrammed as follows:

} Zone of non-derivation (Zone 1)

— Threshold No.1

} Zone of uncertainty (Zone 2)

— Threshold No.2

} Zone of non-distinctness or of indisputable derivation (Zone 3)

— 100%
Scale of genomic conformity

Some breeders are developing such scheme and call the zone No.1 "green zone", in which breeders would have freedom to operate. Zone No.3, the "red zone", where the breeder would know, according to his breeding materials, if his new variety is obviously essentially derived and dependent. Zone No.2 is where there would be uncertainty and where discussion may be appropriate. The threshold levels would be established first as an experiment. They could be further modified according to the experience acquired in the implementation of the scheme.

While this approach may be worthwhile, it also presents some obvious difficulties:

- Breeders have so far been unable to agree on threshold levels for any species;
- Even if the thresholds adopted by the industry had merit, they will not represent an absolute certainty and a court of law could pass judgment on other bases or guidelines.

Nevertheless, this approach does provide some framework in which breeders might proceed.

CONSEQUENCES FOR THE BREEDERS

The concepts of derivation and dependence do not, fortunately, abolish the "breeder's exemption" which is still stated in the 1991 Act. However, "cosmetic" improvement or plagiarism, which could sometimes have allowed the creation of distinct varieties in the sense of the UPOV Convention, will no longer allow the creation of independent varieties. The consequences for the breeders, the farmers and biological diversity more broadly should be positive and will certainly impact the breeder's work.

a) Choice of the parents

Breeders should be certain of their legal access and freedom to use all parent materials employed in their breeding programs. They would have to pay more attention to the results of their breeding work when working with protected varieties within the "breeder's exemption".

b) Breeding methods

Any conventional breeding method could, in theory, provide an essentially derived

variety. Certain methods appear to give a higher risk of developing essentially derived varieties. Among these methods we include:

- natural or induced mutations;
- repeated backcrosses; (discussions still continue on the number of backcrosses which could lead to an essentially derived variety. As shown in the French text of the 1991 Convention, which is of evidence, the authors of the Convention had in mind at least two backcrosses, the word being written in plural. However, it must be noted that the selection pressure exerted after the backcross(es) can have an important effect on the final result).
- selection in an existing variety, for example the choice of clones in a synthetic variety;
- transformation by genetic engineering.

c) Development of technical information

Conformity thresholds for essential derivation, such as presented above, can be defined in the frame of professional agreement (which would be the solution) or, in a case-by-case basis, in decisions by courts of law. In either case, thresholds will come to exist in the years ahead. To know their freedom to operate in relation to such thresholds, breeders will need:

- a good knowledge of the range of phenotypic, molecular and physiological variability of varieties present in the market;
- to know the phenotypic, molecular and physiological profiles of their genetic material and their experimental varieties, as well as their breeding histories and documentation of legal access.

Breeders will need to employ the tools necessary for assessing such profiles in their research programs. Such tools will not only be used for the protection of intellectual property, but should also promote improvement of breeding efficiency.

d) Keeping of breeding books

Conformity thresholds only, at least in the zone of uncertainty (orange zone), will not allow a decision on derivation and dependence. In case of litigation, information on parental material and breeding methods will be needed. Thus, breeders will need to maintain clear and accurate breeding records. We encourage breeders to seek competent professional legal advice on the best ways to develop and maintain these important records.

What is an "Essentially Derived Variety"?

The concept of essentially derived variety was introduced into the 1991 Act of the UPOV Convention in order to avoid plagiarism through mutation, multiple back-crossing and to fill the gap between Plant Breeder's Rights and patents, gap which was becoming important due to the development of the use of patented genetic traits in genetic engineering.

An essentially derived variety is a variety which is distinct and predominantly derived from a protected initial variety, while retaining the essential characteristics of that initial variety.

As indicated as an example in the UPOV Convention, essentially derived varieties may be obtained by the selection of a natural or induced mutant, or of a somaclonal variant, the selection of a variant individual from plants of the initial variety, back-crossing, or transformation by genetic engineering.

The commercialization of an essentially derived variety needs the authorization of the owner of the rights vested in the initial variety.

The concept of essentially derived variety does not at all abolish the Breeder's Exemption, as free access to protected plant varieties for breeding purposes is maintained. It is not a threat to biodiversity. On the contrary, it favors biodiversity, encouraging breeders developing and marketing original varieties.

X. RELATED PROCEEDINGS APPENDIX

Ex parte William D. Griffith, Appeal No. 2004-1968

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte William D. Griffith

Appeal No. 2004-1968[1]
Application No. 10/000,311

MAILED

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U.S. PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS
AND INTERFERENCES

ON BRIEF

Before SCHEINER, ADAMS and GREEN, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 6, 12-19, 21, 24, 26-28 and 30-31. The examiner has indicated that claims 1-5, 7 and 9-11 are allowable. Page 3, Final Rejection, mailed July 1, 2003. Claims 20, 22, 23, 25, 29 and 32 are cancelled. The only remaining pending claim is claim 8. While appellant recognizes (Brief,

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[1] This appeal is substantially similar to Appeal No. 2004-1503, Application No. 09/606,808; Appeal No. 2004-1506; Application No. 09/788,334; Appeal No. 2004-2317, Application No. 09/771,938; Appeal No. 2004-2343, Application No. 09/772,520; and Appeal No. 2005-0396, Application No. 10/077,589, which all share the same assignee, Monsanto Company, the parent of wholly-owned subsidiary DeKalb Genetics Corporation. Accordingly we have considered these appeals together.

page 2) that claim 8 was rejected in the Final Office Action[2], appellant does not include claim 8 as part of the subject matter of the instant appeal. Id., see also, appellant's statement of the Issues on Appeal (Brief, page 3), which does not include claim 8. In this regard, we note, appellant's statement (Brief, page 19), "[t]he rejection of claim 8 concerns a minor clerical error easily corrected by amendment and thus has not been appealed. The examiner also recognized (Answer, bridging sentence, pages 2-3), "the indefiniteness rejection of claim 8 is not being contested...." Since appellant has conceded to the examiner's rejection of claim 8 and has not placed claim 8 before us on appeal, we have not considered claim 8 in our deliberations.

Claims 6, 12, 17, 19, 26 and 30 are illustrative of the subject matter on appeal and are reproduced below. In addition, for convenience, we have reproduced allowable claims 1, 2, and 11 below:

1. Seed of corn inbred line designated LH321, representative seed of said line having been deposited under ATCC Accession No. _____.

2. A corn plant, or parts thereof, produced by growing the seed of claim 1.

6. The corn plant of claim 2, wherein said plant is further defined as comprising a gene conferring male sterility.

11. A method for producing a hybrid corn seed comprising crossing a first inbred parent corn plant with a second inbred parent corn plant and harvesting the resultant hybrid corn seed, wherein said first inbred parent corn plant or second said parent corn plant is the corn plant of claim 2.

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[2] According to the examiner (page 3, Final Rejection, mailed July 1, 2003), claim 8 remains "rejected under 35 U.S.C. [§] 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, as stated on pages 10-11 of the last Office [A]ction." At page 10 of this "last" Office Action, mailed January 13, 2003, the examiner finds "[c]laim 8 is indefinite in its recitation in line 1 of 'the...protoplasts' which lacks antecedent basis in claim 6. Amendment of claim 8, line 1 to delete 'the' before 'cells' would obviate this rejection."

12. A hybrid corn seed produced by the method of claim 11.

17. A method for producing inbred LH321 seed, representative seed of which have been deposited under ATCC Accession No. _____, comprising:
    a) planting a collection of seed comprising seed of a hybrid, one of whose parents is inbred LH321, said collection also comprising seed of said inbred;
    b) growing plants from said collection of seed;
    c) identifying inbred parent plants;
    d) controlling pollination in a manner which preserves the homozygosity of said inbred parent plant; and
    e) harvesting the resultant seed.

19. A method for producing a LH321-derived corn plant, comprising:
    a) Crossing inbred corn line LH321, representative seed of said line having been deposited under ATCC [A]ccession [N]umber _____, with a second corn plant to yield progeny corn seed; and
    b) Growing said progeny corn seed, under plant growth conditions, to yield said LH321-derived corn plant.

26. The corn plant, or parts thereof, of claim 2, wherein the plant or parts thereof have been transformed so that its genetic material contains one or more transgenes operably linked to one or more regulatory elements.

30. A method for developing a corn plant in a corn plant breeding program using plant breeding techniques comprising employing a corn plant, or its parts, as a source of plant breeding material comprising: using the corn plant, or its parts, of claim 2 as a source of said breeding material.

The references relied upon by the examiner are:

Hunsperger et al. (Hunsperger)	5,523,520	Jun. 4, 1996

Eshed et al. (Eshed), "Less-Than-Additive Epistatic Interactions of Quantitative Trait Loci in Tomato," Genetics, Vol. 143, pp. 1807-17 (1996)

Kraft et al. (Kraft), "Linkage Disequilibrium and Fingerprinting in Sugar Beet," Theoretical and Applied Genetics, Vol. 101, pp. 323-36 (2000)

GROUNDS OF REJECTION

Claim 6 stands rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrase "further defined as comprising a gene conferring male sterility."

Claims 26-28 stand rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrase "transformed so that its genetic material contains one or more transgenes."

Claims 6, 12-19, 21, 24, 26-28, 30, and 31 stand rejected under the written description provision of 35 U.S.C. § 112, first paragraph.

Claims 6, 12-19, 21, 24, 26-28, 30 and 31 stand rejected under the enablement provision of 35 U.S.C. § 112, first paragraph.

We reverse.

BACKGROUND

According to paragraph 23 of appellant's specification, the present invention

> relates to the seeds of inbred corn line LH321, to the plants [and plant parts] of inbred corn line LH321 and to methods for producing a corn plant produced by crossing the inbred line LH321 with itself or another corn line, and to methods for producing a corn plant containing in its genetic material one or more transgenes and to the transgenic corn plants produced by that method.

Paragraphs 44-55 of appellant's specification disclose morphologic and "other" characteristics of the inbred corn line LH321. On this record the examiner has indicated that claims drawn to plants, plant parts, and seed of the corn variety designated LH321 are allowable. <u>See</u> <u>e.g.</u>, claims 1-5, 7, and 10, and page 3 of

the Final Rejection, mailed July 1, 2003, wherein the examiner states "[c]laims 1-5, 7 and ... [10] are allowed."

A second aspect of the present invention comprises "hybrid corn seeds and plants produced by crossing the inbred line LH321 with another corn line." Specification, paragraph 23, see also claims 12-16. On this record the examiner has indicated that claims drawn to a process of producing corn seed wherein the process comprises crossing a first parent corn plant with a second parent corn plant are allowable. See e.g., claim 11, and Final Rejection, mailed July 1, 2003, wherein the examiner states claim 11 is allowed.

A third aspect of the present invention is a corn plant from the inbred corn line LH321 further comprising "a cytoplasmic factor that is capable of conferring male sterility" (specification, paragraph 24); or transformed so that its genetic material contains one or more transgenes operably linked to one or more regulatory elements" (see e.g., claims 26-28). As appellant explains (specification, paragraph 13), "[I]t should be understood that the inbred can, through routine manipulation of cytoplasmic or other factors, be produced in a male-sterile form." According to appellant (specification, paragraph 67)

> scientists in the filed of plant biology developed a strong interest in engineering the genome of plants to confer and express foreign genes, or additional , or modified versions of native, or endogenous, genes (perhaps driven by different promoters) in order to alter the traits of a plant in a specific manner. Such foreign additional and/or modified genes are referred to herein collectively as "transgenes". Over the last fifteen to twenty years several methods for producing transgenic plants have been developed, and the present invention, in particular embodiments, also relates to transformed versions of the claimed inbred line.

A final aspect of the present invention is directed to a process of producing an inbred corn plant derived from a plant of the inbred corn line LH321 (see e.g., claims 11, 19 and 30), as well as hybrid plants and seed resulting from such a process (see e.g., claims 12-16). As discussed, supra, the examiner has indicated that claim 11 was allowable. According to appellant's specification (paragraph 56),

> [t]his invention is also directed to methods for producing a corn plant by crossing a first parent corn plant with a second parent corn plant, wherein the first or second corn plant is the inbred corn plant from the line LH321. Further, both first and second parent corn plants may be from the inbred line LH321. Therefore, any methods using the inbred corn line LH321 are part of this invention: selfing, backcrosses, hybrid breeding, and crosses to populations. Any plants produced using inbred corn line LH321 as a parent are within the scope of this invention.

Against this backdrop, we now consider the rejections of record.

DISCUSSION

Definiteness:

Claims 6 and 26-28 stand rejected under 35 U.S.C. § 112, second paragraph. For the following reasons we reverse.

Claim 6

According to the examiner (Answer, page 3), "the recitation 'further defined as comprising a gene conferring male sterility' ... appears to broaden the scope of its parent claim, or to raise some doubt as to whether the corn plant of claim 6 must be male sterile." In this regard, the examiner finds (id.), "[t]he specification does not define plants expressing all the physiological and morphological characteristics of LH321 as being male sterile, or as comprising a

gene that confers male sterility; in fact, the plant of claim 2 (from which claim 6 depends) is male fertile."

Initially, we note that claim 6 does not require that the corn plant express all the physiological and morphological characteristics of LH321. To the contrary, this appears to be the subject matter of claim 5, which the examiner has indicated to be allowable. Page 3, Final Rejection, mailed July 1, 2003. As we understand claim it, claim 6 is drawn to a corn plant, or parts thereof, produced by growing the seed of claim 1, wherein the plant or plant parts further comprise a gene conferring male sterility. In our opinion, claim 6 further limits the subject matter of claim 2, by requiring the plant of claim 2 to further comprise a gene conferring male sterility. Accordingly, we disagree with the examiner that claim 6 fails to further limit the subject matter of claim 2, from which it depends.

In addition, we fail to understand the examiner's statement that "claim 6 does not incorporate all elements of the parent claim [(claim 2)]." As discussed above, claim 6 depends from claim 2, thus all the elements of claim 2 are present in claim 6. Claim 6, however, possesses an additional limitation not found in claim 2 – a gene conferring male sterility. Thus, the male fertile plant of claim 2, is now male sterile as a result of the additional limitation added in claim 6. The examiner provides no evidence that male fertile plants cannot be made male sterile. To the contrary, we recognize the examiner's suggestion that appellant add two new claims drawn to (1) "[a] method of producing a male sterile corn plant comprising transforming the plant of claim 2 with nucleic acid

molecule that confers male sterility; and (2) "[a] male sterile corn plant produced by the ..." suggested method claim above.

Notwithstanding the examiner's assertion to the contrary, in our opinion, a person of ordinary skill in the art would understand what is claimed. Amgen Inc. v. Chugai Pharmaceutical Co., Ltd., 927 F.2d 1200, 1217, 18 USPQ2d 1016, 1030 (Fed. Cir. 1991). Accordingly, we reverse the rejection of claim 6 under 35 U.S.C. § 112, second paragraph.

Claims 26-28

According to the examiner (Answer, page 4), the recitation in claim 26 that the claimed corn plant be "'transformed so that its genetic material contains one or more transgenes' ... appears to broaden the scope of claim 2, or raises some doubt as to whether the plant has all of the traits expressed by the plant of claim 2." According to the examiner (id.), "[s]ince claim 2 is drawn to a plant with defined characteristics and genotypes which exclude the presence of introduced transgenes, it is confusing to characterize these plants as comprising additional genes." In addition, the examiner finds (id.), "[d]ependent claims 27-28 fail to remedy the deficiency of claim 26.

As with the discussion of claim 6 above, claim 26 simply adds a further limitation to claim 2. Specifically, that the plant or plant parts of claim 2 "have been transformed so that its genetic material contains one or more transgenes operably linked to one or more regulatory elements." Accordingly, notwithstanding the examiner's assertion to the contrary, in our opinion, a person of ordinary skill in the art would understand what is claimed. Amgen Inc. v.

Chugai Pharmaceutical Co., Ltd., 927 F.2d 1200, 1217, 18 USPQ2d 1016, 1030 (Fed. Cir. 1991). Accordingly, we reverse the rejection of claims 26-28 under 35 U.S.C. § 112, second paragraph.

Written Description:

Claims 6, 12-19, 21, 24, 26-28, 30 and 31 stand rejected under the written description provision of 35 U.S.C. § 112, first paragraph.

Claims 12-16

According to the examiner (Answer, page 7),

> A review of the language of claims 12-16 indicates that the claims are drawn to a genus, i.e., any and all hybrid corn seeds, and the hybrid corn plants produced by growing said hybrid seeds, wherein the hybrid seeds are produced by crossing inbred corn plant LH321 with any second, distinct inbred corn plant. Variation is expected in the complete genomes and phenotypes of the different hybrid species of the genus, since each hybrid has one non-LH321 parent that is not shared with the other hybrids. Each of the hybrids would inherit a different set of alleles from the non-LH321 inbred parent. As a result, the complete genomic structure of each hybrid, and therefore the morphological and physiological characteristics expressed by each hybrid, would differ.

Accordingly the examiner finds (Answer, page 13),

> [g]iven the lack of written description in the specification regarding any of a multitude of non-LH321 parents to be used in a backcrossing breeding method or any other classical breeding method, one skilled in the art would not have recognized Appellant to have been in possession of the claimed hybrids or progeny plants as recited in claims ... 12-16.

As we understand it, the examiner's concern (see e.g., Answer, pages 15-16) is that since the hybrids inherit only ½ of their diploid[3] set of chromosomes from the plant of corn variety LH321, a person of skill in the art would not have viewed the teachings of the specification as sufficient to demonstrate that appellant was in possession of the genus of hybrid seeds and plants encompassed by claims 12-16. According to the examiner (Answer, page 16), "[t]hat all hybrids will inherit half of their alleles from LH321 does not provide any information concerning the morphological and physiological characteristics that will be expressed by the claimed hybrids."

There is no doubt that the expressed gene products of a hybrid plant, e.g., the morphological and physiological traits, of LH321 and a non-LH321 corn plant will depend on the combination of the genetic material inherited from both parents. See Answer, page 22. Nevertheless, we disagree with the examiner's conclusion (id.) "[t]hat all hybrids will inherit half of their alleles from LH321 does not provide any information concerning the morphological and physiological characteristics that will be expressed by the claimed hybrids."

On these facts, we find it necessary to take a step back and consider what is claimed. As we understand the them, the claims are drawn to a F_1[4] hybrid seed (claims 12, 14 and 15) or plant/plant part (claim 13, and 16) resulting from a

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[3] According to appellant's specification (page 21), "[i]n a diploid cell or organism, the two alleles of a given gene occupy corresponding loci on a pair of homologous chromosomes." Stated differently, diploid means a cell or organism having two sets of chromosomes.

[4] According to appellant's specification (page 3), "[a] single-cross hybrid is produced when two inbred lines are crossed to produce the F_1 progeny."

cross between the inbred corn plant LH321 and a non-LH321 corn plant. The claims do not require the hybrid to express any particular morphological or physiological characteristic. Nor do the claims require that a particular non-LH321 corn variety be used.[5] All that is required by the claims is that the F_1 hybrid has one parent that is a plant of corn variety LH321. Since the examiner has indicated that the seed and the plant of the inbred line LH321 are allowable (see claims 1 and 2), there can be no doubt that the specification provides an adequate written description of this inbred corn line. In addition, the examiner recognizes (Answer, page 7) that appellant's specification describes four exemplary hybrids wherein one parent was a plant of the inbred corn line LH321, see e.g., specification, pages 31-33. Accordingly, it is unclear to this merits panel what additional description is necessary.

As set forth above, the purpose of the written description requirement is to "ensure that the scope of the right to exclude, as set forth in the claims does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification." Reiffin. Here the F_1 hybrid seed or plant has one parent that is a plant of the inbred line LH321. To that end, to satisfy the written description requirement, the inventor "must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention" [emphasis added]. Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). For the foregoing

[5] According to appellant (Brief, page 16), "hundreds or even thousands of other maize plants ... were known at the time the application was filed...."

reasons it is our opinion that appellant has provided an adequate written description of the subject matter set forth in claims 12-16. Accordingly, we reverse the rejection of claims 12-16 under the written description provision of 35 U.S.C. § 112, first paragraph.

<u>Claims 17-19, 21, 24, 30 and 31</u>[6]

According to the examiner (Answer, page 12), "[c]laims 19, 21, 24, 30 and 31 read on processes involving the repeated outcrossing of the exemplified inbred to multitude of genetically unrelated and uncharacterized corn plants for multiple generations." As the examiner explains (<u>id.</u>), "LH321 may be used only in the initial cross, and then the progeny of this cross may be crossed to a multitude of unrelated and uncharacterized corn plants for up to 7 times (as recited in claim 21) or <u>ad infinitum</u> (as claimed in claims 19, 24, 30 and 31)." In this regard, the examiner finds (<u>id.</u>),

> [t]he specification fails to disclose or describe any progeny resulting from such crosses, wherein said progeny could contain only a small portion of the LH321 genome, if any at all, and wherein said progeny would contain a majority of undisclosed and uncharacterized genetic material from a multitude of undisclosed and uncharacterized parents. Furthermore, no description has been provided for the progeny of such crosses with regard to even one morphological trait of said progeny containing a majority of non-LH321 genetic material.

Thus, the examiner concludes (Answer, page 13), "given the lack of an adequate written description of the claimed progeny plants, any method of using said

[6] We note that while the examiner includes (Answer, page 13) claims 17 and 18 with claims 19, 21, 24, 30 and 31 in concluding that the claims are inadequately described, the examiner has explained (Answer, pages 12-13) the basis of this rejection as it applies to claims 19, 21, 24, 30 and 31.

progeny plants in further crosses, as claimed in claims 17-19, 21, 24, 30 and 31, would also be inadequately described.

As we understand the examiner's argument, not only does appellant have to provide a written description of the starting corn plant (LH321), but appellant also must look into the future to determine every other potential corn plant that someone may wish to cross with the LH321 inbred line, and provide written descriptive support for not only every other corn plant that could be crossed with this line, but also the resulting progeny of each cross.

As set forth in Reiffin, the purpose of the written description requirement is to "ensure that the scope of the right to exclude, as set forth in the claims does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification." Here the method of producing an inbred corn plant requires a plant of the inbred corn line LH321 be used as the starting material. To that end, to satisfy the written description requirement, the inventor "must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention" [emphasis added]. Vas-Cath. The examiner has indicated that a claim to the plant of the inbred corn line LH321 is allowable, see e.g., appellant's claim 2. Therefore, in our opinion, there can be no doubt that appellant was in possession of this plant, in addition to a method of using that plant to cross with any other corn plant to produce an inbred corn plant as set forth in claims 17-19, 21, 24, 30 and 31.

In our opinion, it matters not what the other corn plants are, or what the progeny of a cross between the LH321 inbred line and some other corn plant

represents. The inventions of claims 17-19, 21, 24, 30 and 31 are drawn to the use of the LH321 inbred line as the starting material[7] to produce an inbred corn plant. In this regard, we emphasize, the claims are not drawn to a seed or plant that is the result of such a cross. Therefore, we are not persuaded by the examiner's assertion (Answer, page 11),

> [t]he product of the method of claim 31, ... would contain substantial amounts of non-LH321 genetic material [that] has not been characterized or described, because the collection of traits that it possesses has not been disclosed, and because it contains substantial amounts of non-LH321 genetic material which itself has not been described.

Accordingly, for the foregoing reasons, it is our opinion that appellant has "convey[ed] with reasonable clarity to those skilled in the art that, as of the filing date sought, [they were] in possession of the invention," Vas-Cath (emphasis omitted). Therefore, we reverse the rejection of claims 17-19, 21, 24, 30 and 31 under the written description provision of 35 U.S.C. [§] 112, first paragraph.

Claims 6 and 26-28

According to the examiner (Answer, page 13), "[c]laims 26-28 are drawn towards L321 plants further comprising a foreign gene ('transgene') which was previously isolated as a piece of DNA, and then stably inserted into the corn genome by transformation." The examiner finds, however, that "the specification does not describe identified or isolated single loci for all corn plant traits." Answer, page 14. More specifically, the examiner finds (id.), claims 26-28

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[7] See Answer, page 12, wherein the examiner also recognizes that "LH321 may be used only in the initial cross...."

"broadly encompass single loci that have not been discovered or isolated." To the extent that the examiner is asserting that appellant has not provided an enabling disclosure of single loci that have not been identified, we note that to satisfy the written description requirement, the inventor "must convey with reasonable clarity to those skilled in the art that, <u>as of the filing date sought</u>, he or she was in possession of the invention" [emphasis added]. <u>Vas-Cath</u>.

Nevertheless, it may be that the examiner's concern (Answer, page 22), is that "isolated single genes or loci that confer yield enhancement or yield stability ... have not been discovered or isolated...." In this regard, we note the examiner's assertion (<u>id.</u>), "[a]ppellant cannot be in possession of LH321 plants transformed with gene(s) conferring these traits." The examiner, however, provides no evidence to support the assertion that a person of ordinary skill in the art would not recognize that single loci for yield enhancement or yield stability are known in the art. In this regard, we note that appellant discloses (specification, paragraph 133), "[m]any single locus traits have been identified ... examples of these traits include, but are not limited to, ... enhanced nutritional quality, industrial usage, yield stability, and yield enhancement." It appears that the examiner has overlooked appellant's assertion that single locus traits for yield stability and yield enhancement are well known in the art. To this end, we direct the examiner's attention to, for example, United States Patent No.

5,936,145 ('145)[8], issued August 10, 1999, which is prior to the filing date of the instant application. For clarity, we reproduce claims 8, 29 and 39 of the '145 patent below:

> 8. A corn plant having all the physiological and morphological characteristics of corn plant 87DIA4, a sample of the seed of said corn plant having been deposited under ATCC Accession No. 203192.
>
> 29. The corn plant of claim 8, further comprising a single gene conversion.
>
> 39. The single gene conversion of the corn plant of claim 29, where the gene confers enhanced yield stability.

As we understand it, claim 39 of the '145 patent, is drawn to a corn plant which comprises a single gene conversion, wherein the gene confers enhanced yield stability. Thus, contrary to the examiner's assertion it appears, for example, that a single gene that confers enhanced yield stability was known in the art prior to the filing date of the instant application. We remind the examiner "a patent need not teach, and preferably omits, what is well known in the art." Hybritech Incorporated v. Monoclonal Antibodies, Inc. 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986).

We remind the examiner that the inquiry into whether the description requirement is met must be determined on a case-by-case basis and is a question of fact. In re Wertheim, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976). A description as filed is presumed to be adequate; unless or until sufficient evidence or reasoning to the contrary has been presented by the

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[8] We note that the assignee of the '145 patent is DeKalb Genetics Corporation.. The assignee of the present application is Monsanto Company, the parent of wholly-owned subsidiary DeKalb Genetics Corporation.

examiner to rebut the presumption. See e.g., In re Marzocchi, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). The examiner, therefore, must have a reasonable basis to challenge the adequacy of the written description. Accordingly, it is the examiner who has the initial burden of establishing by a preponderance of evidence that a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. Wertheim, 541 F.2d at 263, 191 USPQ at 97. On this record, the examiner provides no evidence to support the assertion that single loci that govern, for example, yield enhancement or enhanced yield stability are not described.

Furthermore, we recognize the examiner's assertion (Answer, page 13) that "one skilled in the art would not have recognized [a]ppellant to have been in possession of the claimed hybrids or progeny plants as recited in claim[ ] 6...." As we understand it, claim 6 is drawn to a corn plant produced by growing the seed of corn inbred line LH321 further defined as comprising a gene conferring male sterility. The examiner has provided no evidence on this record as to why such a corn plant is not adequately described in appellant's specification. In this regard, we note that in the rejection under 35 U.S.C. § 112, second paragraph, the examiner suggested adding two new claims directed at (1) a method of producing a male sterile corn plant comprising transforming the plant of claim 2 with a nucleic acid molecule that confers male sterility, and (2) a male sterile corn plant produced by the method set forth above. Accordingly, we are not persuaded by the examiner's assertion that the specification does not provide an adequate written description of claim 6.

Further, we direct the examiner's attention to claim 16 of related Appeal Nos. 2005-1506 and 2004-2317, which differ from claim 6 on this record only in the variety of corn. In addition, we note that the disclosure of Appeal Nos. 2005-1506 and 2004-2317 and the instant application are substantially similar. However, in both Appeal Nos. 2005-1506 and 2004-2317 the examiner apparently found that appellant's specification provided an adequate written description of claim 16 as no rejection of this claim was made under the written description provision of 35 U.S.C. § 112, first paragraph. Accordingly, we find that the examiner has treated claim 6 in a manner that is inconsistent with the prosecution of similar claims in related applications 09/788,334 and 09/771938, which is the subject matter of Appeal Nos. 2004-1506 and 2004-2317 respectively.

For the foregoing reasons, we are not persuaded by the examiner's arguments. Accordingly, we reverse the rejection of claims 6 and 26-28 under the written description provision of 35 U.S.C. [§] 112, first paragraph.

<u>Summary</u>

For the foregoing reasons, we reverse the rejection of claims 6, 12-19, 21, 24, 26-28, 30 and 31 under the written description provision of 35 U.S.C. § 112, first paragraph.

<u>Enablement</u>:

Claims 6, 12-19, 21, 24, 26-28, 30 and 31 stand rejected under the enablement provision of 35 U.S.C. § 112, first paragraph. The examiner finds

(Answer, page 39), claims 27-30 "are broadly drawn towards inbred corn plant I015011 further defined as having a genome comprising any single locus conversion, encoding any trait; or wherein the single locus was stably inserted into a corn genome by transformation." The examiner presents several lines of argument under this heading. We take each in turn.

I. Retaining the morphological fidelity of the original inbred line:

According to the examiner (Answer, page 30, emphasis added), "[I]t is not clear that single loci may be introduced into the genetic background of a plant through traditional breeding, while otherwise maintaining the genetic and morphological fidelity of the original inbred variety...." With reference to Hunsperger, Kraft, and Eshed the examiner asserts (Answer, page 38), "[t]he rejection raises the issue of how linkage drag hampers the insertion of single genes alone into a plant by backcrossing, while recovering all of the original plant's genome."

We note, however, that claims 26-28 (those which are drawn to a plant transformed with one or more transgenes) do not require that the plant maintain the genetic and morphological fidelity of the original inbred variety. Nor do claims 26-28 require that the resultant plant retain all of the "original plant's genome" as a result of a backcrossing technique. As appellant explains (specification, paragraph 41, emphasis added),

> [s]ingle locus converted or conversion plant refers to plants which are developed by a plant breeding technique called backcrossing wherein essentially all of the desired morphological and physiological characteristics of an inbred are recovered in addition

> to the single locus transferred into the inbred via the backcrossing technique or via genetic engineering.

We find nothing in the appellant's specification to indicate that the single locus converted plant retains <u>all</u> of the morphological and physiological traits, or <u>all</u> of the genome, of the parent plant in addition to the single locus transferred <u>via</u> the backcrossing technique. Accordingly, we disagree with the examiner's assertions to the contrary.

Further, while the examiner does not explain the basis for the rejection of claim 6 under this heading, we note as discussed <u>supra</u>, claim 6 is drawn to a corn plant produced by growing the seed of corn inbred line LH321 further defined as comprising a gene conferring male sterility. In this regard, we note that appellant's specification discloses (paragraph 19), "several methods of conferring genetic male sterility [that are] available [in the art]." We find no evidence in the Answer to suggest this disclosure in appellant's specification is incorrect, or insufficient. In addition, we note that the examiner's rejection of claim 6 is inconsistent with the manner in which a similar claim was treated in related applications 09/788,334 and 09/771,938, the subject matter of Appeal Nos. 2004-1506 and 2004-2317 respectively. Claim 16 of related applications 09/788,334 and 09/771,938, differs from claim 6 of the instant application only with regard to the corn variety. Nevertheless, while the disclosure in these related applications is substantially similar to the disclosure of the instant application, claim 16 was not rejected under the enablement provision of 35

U.S.C. § 112, first paragraph, in either of related applications 09/788,334 or 09/771,938.

Further, we recognize appellant's argument (Brief, page 16) that the examiner failed to establish a nexus between Hunsperger's discussion of petunias; Kraft's discussion of sugar beets; and Eshed's discussion of tomatoes, and the subject matter of the instant application - corn. Absent evidence to the contrary, we agree with appellant (id.), "the [examiner's] indication[9] that the references concerning petunias, sugar beets and tomatoes apply to corn is made without any support." That the examiner has failed to identify (Answer, page Answer, page 38) an example "in the prior art of plants in which linkage drag does not occur," does not mean that linkage drag is expected to occur in corn breeding, which according to appellant (Brief, page 16) "is extremely advanced and well known in the art." In this regard, we agree with appellant (Brief, pages 16-17), the examiner has improperly placed the burden on appellant to demonstrate that the examiner's unsupported assertion is not true. We remind the examiner, as set forth in In re Wright, 999 F.2d 1557, 1561-62, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993):

> When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement.

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[9] See Answer page 38, wherein the examiner asserts "[l]inkage drag appears to be a phenomenon that occurs in all plant types."

II. Corn molecular genetic markers:

According to the examiner (Answer, page 27),

> [n]o guidance has been provided for the identification of any molecular genetic markers such as restriction fragment length polymorphisms [RFLPs] as claimed in claim 31, wherein said genetic molecular markers have been demonstrated to be inked to corn genes conferring agronomically desirable traits, or their use to breed and obtain improved corn genotypes using LH321 as the starting material.

Admittedly, we find the examiner's statement less than clear. However, as we understand it the examiner finds that the specification fails to enable claim 31 because a link between genes conferring agronomically desirable traits and RFLPs has not been established. However, as we understand claim it, claim 31 is drawn to a method of using a plant from the LH321 inbred corn line as the source of plant breeding material in the development of a corn plant in a corn plant breeding program using plant breeding techniques which are selected from the group consisting of: recurrent selection, backcrossing, pedigree breeding, RFLP enhanced selection, genetic marker enhanced selection, and transformation. As appellant discloses (specification, paragraph 3), "[t]he complexity of inheritance influences choice of the breeding method." Appellant then provides a description of various breeding methods. See e.g., specification, paragraphs 3-13. In addition, appellant discloses (specification, ape 14), several reference books wherein "[d]escriptions of other breeding methods that are commonly used for different traits and crops can be found ...." In addition, appellant provides a description of various marker genes. See e.g., specification, paragraphs 69-75. Further, appellant discloses (specification,

paragraph 91), "[f]or the relatively small number of transgenic plants that show higher levels of expression, a genetic map can be generated, primarily via conventional FRLP, PCR and SSR analysis, which identifies the approximate chromosomal location of the integrated DNA molecule." In addition, appellant provides a reference "for exemplary methodologies in this regard..." Id. Faced with this disclosure, the examiner provides no evidence to support his assertion that appellant's specification does not provide an enabling disclosure of the invention set forth in claim 31.

As set forth in In re Marzocchi, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971), the burden is on

> the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure.

On this record, we find only the examiner's unsupported conclusions as to why the specification does not enable the claimed invention. We remind the examiner that nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples. Marzocchi, 439 F.2d at 223, 169 USPQ at 369. In the absence of an evidentiary basis to support the rejection, the examiner has not sustained his initial burden of establishing a prima facie case of non-enablement. In this regard, we note that the burden of proof does not shift to appellant until

the examiner first meets his burden. Marzocchi, 439 F.2d at 223-224, 169 USPQ at 369-370.

Accordingly, we are not persuaded by the examiner's comments.

III. Non-exemplified breeding partners:

The examiner finds (Answer, page 27), "[n]o guidance has been provided regarding the morphological or genetic compositions of a multitude of non-exemplified breeding partners for crossing with LH321...." According to the examiner this is true whether a single cross is preformed to produce a hybrid corn plant as claimed in claims 12-16, or multiple crosses with non-LH321 parents over multiple generations as claimed in claims 19, 21, 24, 30 and 31, with or without multiple non-disclosed parents.[10]

Claims 12-16:

As discussed supra, the examiner has interpreted these claims as directed to the product of a single cross of a LH321 plant and a non-LH321 plant. See Answer, page 5, and 27. Accordingly, as we understand this record, claims 12-16 are drawn to F_1 hybrid seed, plant, or plant parts. The claims do not require the hybrid to express any particular morphological or physiological

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[10] We note that the examiner includes claim 14 in a discussion of "multiple crosses with non-LH321 parents over multiple generations." However, as we understand the claim, claim 14 is drawn to the seed produced by growing the corn plant of claim 13 and harvesting the resultant corn seed. Accordingly, it appears that the examiner has inadvertently included claim 14 together with claims 19, 21, 24, 30 and 31. As we understand claim 14, it should have been included with the rejection of claims 12, 13, 15 and 16. See e.g., Answer, page 5, wherein the examiner's treatment of claims 12-16 together as "drawn towards any hybrid corn seed produced by the process of crossing the inbred corn plant LH321 with any second, distinct, inbred corn plant; and any hybrid corn plant produced by growing said hybrid corn seed (claims 12-16). Accordingly, we have considered the examiner's argument regarding claim 14 together with claims 12, 13, 15 and 16.

characteristic. Nor do the claims require that a particular non-LH321 corn variety be used. All that is required by the claims is that the F_1 hybrid has one parent that is a plant of corn variety LH321.

Since the examiner has indicated that the seed and the plant of the inbred line LH321 are allowable (see claims 1 and 2), there can be no doubt that the specification provides an adequate written description of this inbred corn line. In addition, the examiner recognizes (Answer, page 7) that appellant's specification describes four exemplary hybrids wherein one parent was a plant of the inbred corn line LH321, see e.g., specification, pages 31-33. Accordingly, it is unclear to this merits panel what additional enabling description is necessary. In our opinion, appellant's specification provides an enabling description of F_1 hybrids wherein one parent is a corn plant of the LH321 inbred line.

Claims 17-19, 21, 24, 30 and 31:

We understand these claims to be drawn to methods of producing plants derived from LH321. Stated differently, the claims are drawn to methods of using LH321 inbred corn plants as the starting material to produce other inbred lines. In our opinion, it matters not what the other corn plants are, or what the progeny of a cross between the LH321 inbred line and some other corn plant represents. The inventions of claims 17-19, 21, 24, 30 and 31 are drawn to the use of the LH321 inbred line as the starting material[11] to produce an inbred corn plant. In this regard, we emphasize, these claims are not drawn to a seed or

[11] See Answer, page 12, wherein the examiner also recognizes that "LH321 may be used only in the initial cross...."

plant that is the result of such a cross. The examiner has provided no evidence on this record that person of ordinary skill in the art could not produce another inbred line, which uses a corn plant of the LH321 inbred line as the starting material. Therefore, we are not persuaded by the examiner's unsupported assertions to the contrary.

Accordingly, for the foregoing reasons, we reverse the rejection of claims 6, 12-19, 21, 24, 26-28, 30 and 31 under the enablement provision of 35 U.S.C. § 112, first paragraph.

SUMMARY

We reverse the rejection of claims 6 and 26-28 under 35 U.S.C. § 112, second paragraph.

We reverse the rejection of claims 6, 12-19, 21, 24, 26-28, 30 and 31 under the written description provision of 35 U.S.C. § 112, first paragraph.

We reverse the rejection of claims 6, 12-19, 21, 24, 26-28, 30 and 31 under the enablement provision of 35 U.S.C. § 112, first paragraph.

We do not reach the merits of the rejection of claim 8 under 35 U.S.C. § 112, second paragraph, which was not presented for our review in this appeal.

REVERSED

Toni R. Scheiner Administrative Patent Judge	
Donald E. Adams Administrative Patent Judge	BOARD OF PATENT APPEALS AND INTERFERENCES
Lora M. Green Administrative Patent Judge	

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The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte Francis L. Garing

Appeal No. 2004-2343[1]
Application No. 09/772,520

MAILED
MAR 31 2005
U.S. PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS
AND INTERFERENCES

ON BRIEF[2]

Before SCHEINER, ADAMS and GREEN, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 3, 6, 11, 14-20 and 24-31. The examiner has indicated that claims 1, 2, 5, 7-10, 12, 13 and 21-23 are allowable. Claim 4 is cancelled.

[1] This appeal is substantially similar to Appeal No. 2004-1503, Application No. 09/606,808; Appeal No. 2004-1506, Application No. 09/788,334; Appeal No. 2004-1968, Application No. 10/00,0311; Appeal No. 2004-2317, Application No. 09/771,938; and Appeal No. 2005-0396, Application No. 10/077,589, which all share the same assignee, Monsanto Company, the parent of wholly-owned subsidiary DeKalb Genetics Corporation. Accordingly we have considered these appeals together.

[2] We note that appellant waived his request for Oral Hearing. See Paper received December 3, 2004.

Claims 3, 6, 15, 16, 17, 27, 28 and 30 are illustrative of the subject matter on appeal and are reproduced below. In addition, for convenience, we have reproduced allowable claims 2 and 5 below:

2. A population of seed of the corn variety I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228.

3. The population of seed of claim 2, further defined as an essentially homogeneous population of seed.

5. A corn plant produced by growing a seed of the corn variety I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228.

6. The corn plant of claim 5, having:
   (a) an SSR profile in accordance with the profile shown in Table 6; or
   (b) an isozyme typing profile in accordance with the profile shown in Table 7.

15. A corn plant capable of expressing all the physiological and morphological characteristics of the corn variety I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228.

16. The corn plant of claim 15, further comprising a nuclear or cytoplasmic gene conferring male sterility.

17. A tissue culture of regenerable cells of a plant of corn variety I026458, wherein the tissue is capable of regenerating plants capable of expressing all the physiological and morphological characteristics of the corn variety I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228.

27. The corn plant of claim 5, further defined as having a genome comprising a single locus conversion.

28. The corn plant of claim 27, wherein the single locus was stably inserted into a corn genome by transformation.

30. The corn plant of claim 27, wherein the locus confers a trait selected from the group consisting of herbicide tolerance; insect resistance; resistance to bacterial, fungal, nematode or viral disease; yield enhancement; waxy

starch; improved nutritional quality; enhanced yield stability; male sterility and restoration of male fertility.

The references relied upon by the examiner are:

Hunsperger et al. (Hunsperger)	5,523,520	Jun. 4, 1996

Eshed et al. (Eshed), "Less-Than-Additive Epistatic Interactions of Quantitative Trait Loci in Tomato," Genetics, Vol. 143, pp. 1807-17 (1996)

Kraft et al. (Kraft), "Linkage Disequilibrium and Fingerprinting in Sugar Beet," Theoretical and Applied Genetics, Vol. 101, pp. 323-36 (2000)

GROUNDS OF REJECTION

Claim 3 stands rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrase "an essentially homogeneous population of seed."

Claim 14 stands rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrase "[a]n essentially homogeneous population of corn plants produced by growing the seed of the corn variety I026458."

Claims 6 and 11 stand rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrase "in accordance with."

Claims 15, and 17-20[3] stand rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrase "capable of expressing."

[3] According to the examiner (Answer, pages 12 and 13), since claims 18 and 19 depend from claim 17 they are included in this rejection.

Claims 16 and 27-30[4] stand rejected under 35 U.S.C. § 112, second paragraph as failing to limit the scope of the claims from which they depend.

Claim 28 stands rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of "the article 'a' in the recitation 'wherein the single locus was stably inserted into a corn genome.'"

Claim 30 stands rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrases "yield enhancement," "improved nutritional quality," and "enhanced yield stability."

Claims 6, 11, 24-31[5] stand rejected under the written description provision of 35 U.S.C. § 112, first paragraph.

Claims 27-30 stand rejected under the enablement provision of 35 U.S.C. § 112, first paragraph.

We reverse.

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[4] According to the examiner (Answer, page 4), "[c]laims ... 27-30 ... stand rejected under 35 U.S.C. [§] 112, second paragraph..." The examiner, however, provides no explanation as to why claim 29 is rejected. We can only assume that since claim 29, as well as claims 28 and 30, each depend from claim 27, they are rejected for the same reason as claim 27. Accordingly, we have included claims 28-30 with this ground of rejection.

[5] We recognize the examiner's statement (Answer, page 3), "[c]laim 26 was objected to in the Office Action mailed 23 September 2003, as being in improper dependent form for failing to further limit the subject matter of previous claim. Appellant did not address this objection. An objection to a claim, however, is the subject matter of a petition, and is not properly before us on appeal. Nevertheless, we make the following observation regarding claim 26, and encourage the examiner and appellant to work together to remedy this issue, prior to any further action on the merits.

According to appellant's specification (page 20), a F_1 hybrid is "[t]he first generation progeny of the cross of two plants." Therefore, as we understand the prosecution history as well as the language of the claims, claims 24 and 25 to refer to F_1 hybrids. In this regard, we note that similar claims, directed to a different corn variety, were presented for our review in Appeal Nos. 2004-1506 and 2004-2317. During the oral hearing in Appeal Nos. 2004-1506 and 2004-2317, appellant's representative confirmed that all claims drawn to hybrid plants or hybrid seeds (see e.g., claims 24 and 25) refer to F_1 hybrids. Accordingly, it appears that claim 26 fails to further limit claim 25 from which it depends.

BACKGROUND

The present "invention relates to inbred corn seed and plants of the variety designated I026458, and derivatives and tissue cultures thereof." Specification, page 2. According to appellant (specification, page 28), "[a] description of the physiological and morphological characteristics of corn plant I026458 is presented in Table 3" of the specification, pages 28-29. On this record the examiner has indicated that claims drawn to plants, plant parts, and seed of the corn variety designated I026458 are allowable. See e.g., claims 1, 2, 5, 7-10, 12 and 13, and Answer, page 2, wherein the examiner states "[c]laims 1, 2, 5, 7-10, 12 [and] 13 ... are allowed."

A second aspect of the present invention comprises hybrid plants and processes "for producing [first generation (F_1) hybrid[6]] corn seeds or plants, which ... generally comprise crossing a first parent corn plant with a second parent corn plant, wherein at least one of the first or second parent corn plants is a plant of the variety designated I026458." Specification, pages 7-9. On this record the examiner has indicated that claims drawn to a process of producing corn seed wherein the process comprises crossing a first parent corn plant with a second parent corn plant are allowable. See e.g., claims 21-23 and Answer, page 2, wherein the examiner states claims "21-23 are allowed."

[6] According to the specification (page 21), a F_1 hybrid is "[t]he first generation progeny of the cross of two plants." During oral hearing, appellant confirmed that all claims drawn to hybrid plants or hybrid seeds (see e.g., claims 24 and 25) refer to F_1 hybrids.

A third aspect of the present invention comprises single locus converted plants of the corn variety I026458. Specification, page 6. As appellant explains (specification, page 23, emphasis added), single locus converted (conversion) plants are those plants

> which are developed by a plant breeding technique called backcrossing wherein essentially all of the desired morphological and physiological characteristics of an inbred are recovered in addition to the characteristics conferred by the single locus transferred into the inbred via the backcrossing technique. A single locus may comprise one gene, or in the case of transgenic plants, one or more transgenes integrated into the host genome at a single site (locus).

As appellant explains (specification, page 31):

> Many single locus traits have been identified that are not regularly selected for in the development of a new inbred but that can be improved by backcrossing techniques. Single locus traits may or may not be transgenic; examples of these traits include, but are not limited to, male sterility, waxy starch, herbicide resistance, resistance for bacterial, fungal, or viral disease, insect resistance, male fertility, enhanced nutritional quality, industrial usage, yield stability, and yield enhancement. These genes are generally inherited through the nucleus, but may be inherited through the cytoplasm. Some known exceptions to this are genes for male sterility, some of which are inherited cytoplasmically, but still act as single locus traits.

A final aspect of the present invention is directed to a process of producing an inbred corn plant derived from a plant of the corn variety I026458. See e.g., claim 31. According to appellant's specification (bridging paragraph, pages 10-11),

> the present invention provides a method of producing an inbred corn plant derived from the corn variety I026458, the method comprising the steps of: (a) preparing a progeny plant derived from corn variety I026458, wherein said preparing comprises crossing a plant of the corn variety I026458 with a second corn plant, and

> wherein a sample of the seed of corn variety I026458 has been deposited under ATCC Accession No. PTA-3228; (b) crossing the progeny plant with itself or a second plant to produce a seed of a progeny plant of a subsequent generation; (c) growing a progeny plant of a subsequent generation from said seed of a progeny plant of a subsequent generation and crossing the progeny plant of a subsequent generation with itself or a second plant; and (d) repeating steps (c) and (d) for an addition 3-10 generations to produce an inbred corn plant derived from the corn variety I026458. In the method, it may be desirable to select particular plants resulting from step (c) for continued crossing according to steps (b) and (c). By selecting plants having one or more desirable traits, an inbred corn plant derived from the corn variety I026458 is obtained which possesses some of the desirable traits of corn variety I026458 as well potentially other selected traits.

According to the examiner (Answer, page 36), "[t]he patentability of the method of claim 31 does not lie in the acts of the process, which are the simple acts of crossing corn plants, allowing progeny seed to be produced, and growing progeny plants from the seed...." Therefore, as we understand this aspect of the claimed invention (e.g., claim 31), the intent is not to claim a specific inbred corn plant resulting from the claimed process. See claim 31. Instead, as we understand it, claim 31 is drawn to a process wherein an inbred corn plant is derived from the corn variety I026458.

As appellant explains (specification, page 3),

> The development of uniform corn plant hybrids requires the development of homozygous inbred plants, the crossing of these inbred plants, and the evaluation of the crosses. Pedigree breeding and recurrent selection are examples of breeding methods used to develop inbred plants from breeding populations. Those breeding methods combine the genetic backgrounds from two or more inbred plants or various other broad-based sources into breeding pools from which new inbred plants are developed by selfing and selection of desired phenotypes. The new inbreds are crossed with other inbred plants and the hybrids from these crosses are evaluated to determine which of those have commercial potential.

We emphasize, that while "new inbreds" having commercial potential may result from the method set forth in claim 31, the claim does not encompass any specific plant that is produced as a result of the method. Rather the claim encompasses only a method of producing an inbred corn plant that is "derived" from the corn variety I026458. The examiner has indicated that a claim drawn to a corn plant of the corn variety I026458 is allowable. See e.g., claim 5, and Answer, page 2, wherein the examiner states that claim 5 is allowed.

Against this backdrop, we now consider the rejections of record.

DISCUSSION

Definiteness:

Claims 3, 6, 11, 14-20 and 27-30 stand rejected under 35 U.S.C. § 112, second paragraph. For the following reasons we reverse.

Claim 3

Claim 3 depends from independent claim 2, and stands rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrase "an essentially homogeneous population of seed...." Answer, page 4. According to the examiner (id.), claim 2 is drawn to "'[a] population of seed of the corn variety I026458, wherein a sample of the seed of the corn variety I026458 was deposited under ATCC Accession No. PTA-3228." Thus, the examiner finds (Answer, page 5), the population of seed set forth in claim 2 "is a homogeneous population of seed of corn variety I026458." Accordingly, the examiner finds

(id.), "[t]he recitation, 'essentially homogeneous,' in claim 3 ... appear[s] to be superfluous."

However, as disclosed in appellant's specification (page 5),

> [e]ssentially homogeneous populations of inbred seed are those that consist essentially of the particular inbred seed, and are generally free from substantial numbers of other seed, so that the inbred seed forms between about 90% and about 100% of the total seed, and preferably, between about 95% and about 100% of the total seed.

Accordingly, we disagree with the examiner's assertion (Answer, page 6) that claim 3 is unclear simply because it may contain seed other than the seed of the corn variety I026458. We remind the examiner that claim language must be analyzed "not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary skill in the pertinent art." In re Moore, 439 F.2d 1232, 1235, 169 USPQ 236, 238 (CCPA 1971). Here, notwithstanding appellant's comments[7], it is our opinion that a person of ordinary skill in the art would recognize that an essentially homogeneous population of seed of the corn variety I026458 is a population of seed that is generally free from substantial numbers of other seed, e.g., wherein corn variety I026458 seed forms between about 90% and about 100% of the total seed in the population.[8]

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[7] According to appellant (Brief, page 7), an essentially homogeneous population of seed, is a population of seed that could be of non-uniform size and shape.

[8] Cf. the examiner's statement (Answer, page 6), "amending claim 3 to read '[a]n essentially homogeneous population of corn seeds consisting essentially of seed of claim 1', would obviate this rejection."

Accordingly, we reverse the rejection of claim 3 under 35 U.S.C. § 112, second paragraph.

Claim 14

Claim 14 stands rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrase "[a]n essentially homogeneous population of corn plants produced by growing the seed of the corn variety I026458." Answer, page 6. According to the examiner (id.), "[t]he I026458 seed can only produce I026458 plants. ... [Therefore,] [t]he population can ... only consist of I026458 plants." Accordingly, the examiner finds it unclear "why the population is referred to as 'essentially homogeneous,' since such populations can comprise more than one variety of plant." Answer, bridging sentence, pages 6-7.

As appellant discloses (specification, page 6), "[t]he population of inbred corn seed of the invention can further be particularly defined as being essentially free from hybrid seed. The inbred seed population may be separately grown to provide an essentially homogeneous population of inbred corn plants designated I026458." As we understand the claim, growing the seed of claim 3, for example, would produce an essentially homogeneous population of corn plants of the corn variety I026458.[9]

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[9] Cf. The examiner's statement (Answer, page 8), amending claim 14 "to read, '[a]n essentially homogeneous population of corn plants produced by growing a population of corn seed consisting essentially of the seed of corn plant I026458...' would obviate the rejection."

In addition, we direct the examiner's attention to Appeal No. 2005-0396, wherein a claim similar to claim 14 was presented for our review. In Appeal No. 2005-0396, the examiner of record indicated that claim 14, directed to "[a]n essentially homogeneous population of corn plants produced by growing the seed of the corn variety I180580...." was allowable. Accordingly, we find that the examiner has treated claim 14 in a manner that is inconsistent with the prosecution of claim 14 in 2005-0396. As we understand it, the only difference between claim 14 as it appears in Appeal No. 2005-0396 and the instant appeal is the variety of corn seed from which the plant is produced.

Accordingly we reverse the rejection of claim 14 under 35 U.S.C. § 112, second paragraph.

Claims 6 and 11

Claims 6 and 11 stand rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrase "in accordance with." According to the examiner (Answer, page 9), it is unclear if a plant "that generally follows the trend of the profile of Table 6, but which differs at one or a few loci, [would] be considered in 'conformity' or 'in accordance' with the profile of Table 6."

On this record, we understand the phrase "in accordance with" as it is used in claims 6 and 11 to mean "the same"[10] Stated differently, we understand the claims to read:

[10] Cf. Appeal Nos. 2004-1506 and 2004-2317, which use similar language for claims directed to different corn varieties. In this regard, we note that during the February 10, 2005 oral hearing in Appeal Nos. 2004-1506 and 2004-2317, appellant's representative confirmed that the phrase "in accordance with" was intended to mean "the same".

6. The corn plant of claim 5, having:
   (a) the same SSR profile as shown in Table 6; or
   (b) the same isozyme typing profile as shown in Table 7.

11. The plant part of claim 10, wherein said cell is further defined as having:
   (a) The same SSR profile as shown in Table 6; or
   (b) The same isozyme typing profile as shown in Table 7.

Accordingly we reverse the rejection of claims 6 and 11 under 35 U.S.C. § 112, second paragraph.

Claims 15 and 17-20

Claims 15, and 17-20 stand rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrase "capable of expressing," or "capable of regenerating." According to the examiner (Answer, page 9), the claims do "not make clear if the plant actually expresses the traits, or when or under what conditions the traits are expressed." In this regard, the examiner finds (Answer, page 10),

> while the plant has the capacity to express the characteristics, for some reason it may not. Certain characteristics of a plant are expressed only at certain times of its life cycle, and are incapable of being expressed at other times. The colors of flower parts such as silks, or fruit parts such as husks, are examples. The promoters of many genes conferring traits require a transcription factor to become active. Is a plant that has such a gene, but not the transcription factor, considered "capable of expressing" that gene, and the trait associated with that gene, and is such a plant encompassed by the claims?

To address the examiner's concerns, we find it sufficient to state that if a plant has the capacity to express the claimed characteristics it meets the requirement of the claim regarding "capable of," notwithstanding that due to a particular phase of the life cycle the plant is not currently expressing a particular

characteristic. Alternatively, if a plant is incapable of expressing the claimed characteristics at any phase of the life cycle, because it lacks, for example, the "transcription factor" required for expression – such a plant would not meet the requirement of the claim regarding "capable of."

Here, we find the examiner's extremely technical criticism to be a departure from the legally correct standard of considering the claimed invention from the perspective of one possessing ordinary skill in the art.[11] In our opinion, a person of ordinary skill in the art would understand what is claimed. Amgen Inc. v. Chugai Pharmaceutical Co., Ltd., 927 F.2d 1200, 1217, 18 USPQ2d 1016, 1030 (Fed. Cir. 1991). We find the same to be true for the phrase "capable of" as set forth in claims 17-20.

Accordingly we reverse the rejection of claims 15, and 17-20 under 35 U.S.C. § 112, second paragraph.

Claims 16 and 27-30

Claims 16 and 27-30 stand rejected under 35 U.S.C. § 112, second paragraph as failing to limit the scope of the claims from which they depend. According to the examiner (Answer, page 11), since the plant set forth in claim 16 is male sterile it cannot express all the morphological and physiological characteristics of the male fertile corn variety I026458. Similarly, the examiner finds it unclear whether the plant set forth in claim 27 has all the characteristics of the plant set forth in claim 5, from which claim 27 depends. Id. In response,

[11] Cf. Digital Equipment Corp. v. Diamond, 653 F.2d 701, 724, 210 USPQ 521, 546 (CA 1981).

appellant asserts (Brief, pages 9-10), claims 16 and 27 simply add a further limitation to the claims from which they depend. We agree.

For example, claim 16 reads on a corn plant capable of expressing all the physiological and morphological characteristics of the corn variety I026458, further comprising a nuclear or cytoplasmic gene conferring male sterility. In our opinion, the claims reasonably apprise those of skill in the art of their scope. Amgen, As set forth in Shatterproof Glass Corp. v. Libbey-Owens Ford Co., 758 F.2d 613, 624, 225 USPQ 634, 641 (Fed. Cir. 1985), "[i]f the claims, read in the light of the specifications, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, the courts can demand no more."

Accordingly we reverse the rejection of claims 16 and 27-30 under 35 U.S.C. § 112, second paragraph.

Claim 28

Claim 28 stands rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of "the article 'a' in the recitation 'wherein the single locus was stably inserted into a corn genome.'" According to the examiner (Answer, page 13), "[t]he recitation does not make clear if the genome is that of I026458 or that of a different corn plant."

According to appellant's specification (page 23, emphasis removed), a "Single Locus Converted (Conversion) Plant" refers to

> [p]lants which are developed by a plant breeding technique called backcrossing wherein essentially all of the desired morphological and physiological characteristics of an inbred are recovered in

> addition to the characteristics conferred by the single locus transferred into the inbred via the backcrossing technique. A single locus may comprise one gene, or in the case of transgenic plants, one or more transgenes integrated into the host genome at a single site (locus).

Accordingly, we agree with appellant (Brief, page 12) "[t]he single locus referred to in claim 28 may or may not have been directly inserted into the genome of the claimed plant." As we understand the claim, and arguments of record, claim 28 presents two possibilities: (1) the single locus is directly inserted into the claimed plant and nothing further need be done; or (2) the single locus is directly inserted into a different plant, which is then used to transfer the single locus to the claimed plant through use of the plant breeding technique known as backcrossing.

In our opinion, the claim reasonably apprises those of skill in the art of its scope. Amgen. Accordingly, we reverse the rejection of claim 28 under 35 U.S.C. § 112, second paragraph.

Claim 30

Claim 30 stands rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrases "yield enhancement," "improved nutritional quality," and "enhanced yield stability." According to the examiner the terms "yield enhancement," "improved nutritional quality," and "enhanced yield stability" are relative and have no definite meaning. Answer, page 14. The examiner is correct (Answer, page 14), when a word of degree is used appellant's specification must provide some standard for measuring that degree.

Seattle Box. Co. v. Industrial Crating & Packing, Inc., 731 F.2d 818, 826, 221 USPQ 568, 573-574 (Fed. Cir. 1984).

On this record, appellant asserts (Brief, page 12), it is "understood the enhancement of yield or yield stability and improved nutritional quality is relative to a plant lacking the single locus. The metes and bounds of the claim are thus fully understood by one of skill in the art and the use of the terms is not indefinite." On reflection, we agree with appellant. The fact that some claim language is not mathematically precise does not per se render the claim indefinite. Seattle Box. As set forth in Shatterproof Glass, "[i]f the claims, read in the light of the specifications, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, the courts can demand no more." In our opinion, a person of ordinary skill in the art would have understood the enhancement of yield or yield stability and improved nutritional quality is relative to a plant lacking the single locus.

Accordingly we reverse the rejection of claim 30 under 35 U.S.C. § 112, second paragraph.

Written Description:

Claims 6, 11, 24, 25 and 27-31 stand rejected under 35 U.S.C. § 112, first paragraph, as the specification fails to adequately describe the claimed invention. For the following reasons, we reverse.

Claims 24-26[12]

Claims 24-26 ultimately depend from claim 23. On this record, the examiner has indicated that claim 23 is allowable. Answer, page 2. The examiner finds (Answer, page 16), claims 24-26 are drawn to a hybrid plant or seed "produced by crossing inbred corn plant I026458 with any second, distinct inbred corn plant."

As we understand it, based on this construction of claims 24-26, the examiner is of the opinion that since the hybrids inherit only ½ of their diploid[13] set of chromosomes from the plant of corn variety I026458, a person of skill in the art would not have viewed the teachings of the specification as sufficient to demonstrate that appellant was in possession of the genus of hybrid seeds and plants encompassed by claims 24-26. According to the examiner (Answer, page 22), "[t]he fact that any hybrid plant will inherit half of its alleles from I026458 then does not provide sufficient description of the morphological and physiological characteristics expressed by the claimed hybrid plants."

There is no doubt that the expressed gene products of a hybrid plant, e.g., the morphological and physiological traits, of I026458 and a non-I026458 corn plant will depend on the combination of the genetic material inherited from both parents. See Answer, page 23. Nevertheless, we disagree with the examiner's

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[12] We recognize, as does the examiner (Answer, page 22) that appellant's reference to claims 22-26 (Brief, page 14) was intended to be a reference to claims 24 and 25.

[13] According to appellant's specification (page 21), diploid means "a cell or organism having two sets of chromosomes."

conclusion (id.) that "[t]he fact that any hybrid plant will inherit half of its alleles from I026458 then does not provide sufficient description of the morphological and physiological characteristics expressed by the claimed hybrid plants."

On these facts, we find it necessary to take a step back and consider what is claimed. The claims are drawn to a F_1 hybrid seed (claim 24) or plant (claim 25) resulting from a cross between a plant of corn variety I026458 and a non-I026458 corn variety. The claims do not require the hybrid to express any particular morphological or physiological characteristic. Nor do the claims require that a particular non-I026458 corn variety be used.[14] All that is required by the claims is that the hybrid has one parent that is a plant of corn variety I026458. Since the examiner has indicated that the seed and the plant of the corn variety I026458 are allowable (see claims 1 and 5), there can be no doubt that the specification provides an adequate written description of this corn variety. In addition, the examiner appears to recognize (Answer, pages 24-25) that appellant's specification describes an exemplary hybrid wherein one parent was a plant of the corn variety I026458, see e.g., specification, pages 53-57. Accordingly, it is unclear to this merits panel what additional description is necessary.

As set forth in Reiffin v. Microsoft Corp., 214 F.3d 1342, 1345, 54 USPQ2d 1915, 1917 (Fed. Cir. 2000), the purpose of the written description

[14] According to appellant (Brief, page 16), "hundreds or even thousands of different inbred corn lines were well known to those of skill in the art prior to the filing [date] of the instant application, each of which could be crossed to make a hybrid plant with in the scope of the claims."

requirement is to "ensure that the scope of the right to exclude, as set forth in the claims does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification." Here the hybrid seed or plant has one parent that is a plant of the corn variety I026458. To that end, to satisfy the written description requirement, the inventor "must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention" [emphasis added]. Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). For the foregoing reasons it is our opinion that appellant has provided an adequate written description of the subject matter set forth in claims 24-26.[15]

We recognize the examiner's argument relating to SSR and isozyme markers (Answer, pages 28-33), as well as the examiner's arguments concerning a correlation between the hybrid's genome structure and the function of the hybrid plant (Answer, pages 24-27). However, for the foregoing reasons, we are not persuaded by these arguments.

Claims 6 and 11

Claims 6 and 11 depend ultimately upon claim 5. On this record, the examiner has indicated that claim 5 is allowable. Answer, page 2.

According to the examiner (Answer, page 17), while the specification provides the locus names and allele numbers of the SSR markers, the specification does not provide the actual nucleotide sequences that make up the

[15] Again, we note as set forth in n. 3. that claim 26 does not appear to further limit the scope of claim 25 from which it depends.

markers. According to the examiner (id.), "names of loci alone do not describe the structures of the markers themselves. Without a description of the sequences of the markers, one cannot confirm their presence." In response, appellant points out (Brief, page 13), "the SSR markers were from Celera AgGen, Inc., which provides a commercial service for genotyping of maize varieties." In other words, a person of ordinary skill in the art could use the commercially available service provided by Celera AgGen, Inc. to determine whether a corn plant produced by growing a seed of the corn variety I026458 has an SSR profile which is the same as that shown in Table 6. Therefore, it is unclear to this panel why the examiner believes that such a disclosure fails to provide adequate written descriptive support for the claimed invention.[16] Accordingly, we are not persuaded by the examiner's argument.

Regarding the isozyme typing profile, the examiner finds (Answer, page 17), "Table 7 provides names of loci where isozyme markers reside, for three different corn plants, and a numerical value that represents the numbers of alleles at isozyme loci types. The nucleotide sequences that make up these loci are not described." In response, appellant points out (Brief, page 13), the isozyme "markers are well known and isozyme analysis in general [is] very well known having been used for decades." In this regard, we remind the examiner

[16] We are not persuaded by the examiner's assertion (Answer, page 31) "that the [commercially available] service used to detect SSR markers is currently available is not a guarantee that it will remain so for the life of a patent issuing from the application." Cf. In re Metcalfe, 410 F.2d 1378, 1382, 161 USPQ 789, 792-3 (CCPA 1969).

that the inquiry into whether the description requirement is met must be determined on a case-by-case basis and is a question of fact. In re Wertheim, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976). A description as filed is presumed to be adequate; unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption. See e.g., In re Marzocchi, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). The examiner, therefore, must have a reasonable basis to challenge the adequacy of the written description. Accordingly, it is the examiner who has the initial burden of establishing by a preponderance of evidence that a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. Wertheim, 541 F.2d at 263, 191 USPQ at 97. On this record, the examiner provides no evidence to support the assertion that simply because appellant has not provided the sequences that make up the loci for particular isozymes, appellant's specification does not adequately describe the claimed invention. Accordingly, we are not persuaded by the examiner's argument.

The examiner finds (Answer, page 21), claims 6 and 11 require that the claimed plant or plant cell exhibit either the claimed SSR profile or the isozyme profile. According to the examiner (id.), "[t]he genome of the cells of the I026458 seed deposited with the ATCC has both the SSR profile and the isozyme typing profile shown in Tables 6 and 7 for that plant. No plant is described in the specification that has one genetic marker profile but not the other." The examiner's concern appears to be misplaced. To the extent that the examiner is

concerned that the claim is open to read on a plant other than a corn plant produced by growing a seed of the corn variety I026458, we remind the examiner that both claims 6 and 11 ultimately depend from claim 5[17], which is drawn to "[a] corn plant produced by growing a seed of the corn variety I026458...."

It appears that the examiner may have read claims 6 and 11 as drawn to a corn plant or plant cell having only one of the recited profiles. However, as we understand claims 6 and 11, determining whether the claimed corn plant (claim 6) or plant cell (claim 11) has one of the profiles does not mean that the plant, or plant cell would not also exhibit the other profile.

In addition, we direct the examiner's attention to claims 6 and 11 of Appeal No. 2005-0396. As we understand it, notwithstanding differences in the SSR and isozyme profiles, the disclosure in the specification as well as the language of the claims is substantially similar to that of the instant application. Nevertheless, the examiner in Appeal No. 2005-0396 apparently found that appellant's specification provided an adequate written description of the claimed invention as no rejection of claims 6 and 11 was made under the written description provision of 35 U.S.C. § 112, first paragraph in Appeal No. 2005-0396. Accordingly, we find that the examiner has treated claims 6 and 11 in a manner that is inconsistent with the prosecution of similar claims in related application 10/077,589, which is the subject matter of Appeal No. 2005-0396.

[17] The examiner has indicated that claim 5 is allowable. Answer, page 2.

For the foregoing reasons, we are not persuaded by the examiner's arguments.

Claims 27-30

According to the examiner (Answer, page 18), "[c]laims 27-30 are drawn towards I026458 plants further comprising a single locus conversion, or wherein the single locus was stably inserted into a corn genome by transformation." The examiner finds, however, that "the specification does not describe identified or isolated single loci for all corn plant traits." Id. More specifically, the examiner finds (id.), claims 27-30 "broadly encompass single loci that have not been discovered or isolated." To the extent that the examiner is asserting that appellant has not provided an enabling disclosure of single loci that have not been identified, we note that to satisfy the written description requirement, the inventor "must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention" [emphasis added]. Vas-Cath.

Nevertheless, it may be that the examiner's concern (Answer, page 35), is that "single genes that alone govern 'yield enhancement' or 'enhanced yield stability' have not been discovered." In this regard, the examiner asserts (Answer, page 36), "the references cited in the specification do not describe isolated single genes or loci that confer yield enhancement or yield stability." Therefore, the examiner concludes (id.), "[a]ppellant cannot be in possession of plants further comprising single loci that have yet to be identified." The examiner, however, provides no evidence to support the assertion that a person

of ordinary skill in the art would not recognize that single loci for yield enhancement or yield stability are known in the art. In this regard, we note that appellant discloses (specification, page 31), "[m]any single locus traits have been identified ... examples of these traits include, but are not limited to, ... enhanced nutritional quality, industrial usage, yield stability, and yield enhancement." It appears that the examiner has overlooked appellant's assertion that single locus traits for yield stability and yield enhancement are well known in the art. To this end, we direct the examiner's attention to, for example, United States Patent No. 5,936,145 ('145)[18], issued August 10, 1999, which is prior to the filing date of the instant application. For clarity, we reproduce claims 8, 29 and 39 of the '145 patent below:

> 8. A corn plant having all the physiological and morphological characteristics of corn plant 87DIA4, a sample of the seed of said corn plant having been deposited under ATCC Accession No. 203192.
>
> 29. The corn plant of claim 8, further comprising a single gene conversion.
>
> 39. The single gene conversion of the corn plant of claim 29, where the gene confers enhanced yield stability.

As we understand it, claim 39 of the '145 patent, is drawn to a corn plant which comprises a single gene conversion, wherein the gene confers enhanced yield stability. Thus, contrary to the examiner's assertion it appears, for example, that a single gene that confers enhanced yield stability was known in the art prior to the filing date of the instant application. We remind the examiner "a patent need

[18] We note that the assignee of the '145 patent is DeKalb Genetics Corporation. The assignee of the present application is Monsanto Company, the parent of wholly-owned subsidiary DeKalb Genetics Corporation.

not teach, and preferably omits, what is well known in the art." Hybritech Incorporated v. Monoclonal Antibodies, Inc. 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986).

We remind the examiner that the inquiry into whether the description requirement is met must be determined on a case-by-case basis and is a question of fact. In re Wertheim, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976). A description as filed is presumed to be adequate; unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption. See e.g., In re Marzocchi, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). The examiner, therefore, must have a reasonable basis to challenge the adequacy of the written description. Accordingly, it is the examiner who has the initial burden of establishing by a preponderance of evidence that a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. Wertheim, 541 F.2d at 263, 191 USPQ at 97. On this record, the examiner provides no evidence to support the assertion that single loci that govern, for example, yield enhancement or enhanced yield stability are not described.

For the foregoing reasons, we are not persuaded by the examiner's arguments.

Claim 31

Claim 31 is drawn to a method of producing an inbred corn plant derived from the corn variety I026458. The claimed method begins by crossing a plant of the corn variety I026458 with any other corn plant. The method requires that the

progeny corn plant be crossed either to itself, or with any other corn plant, and that the progeny of this cross be further crossed to itself, or with another corn plant, and so on throughout several generations. As we understand it, claim 31, in its simplest form, is directed to a method of using a plant of the corn variety I026458 to produce an inbred corn plant.

Nevertheless, the examiner finds (Answer, page 19), "[a] review of the claim indicates that hybrid progeny of corn plant I026458 are required to perform further crosses, and that progeny of subsequent generations can be further outcrossed with different corn plants." Therefore, the examiner concludes (id.), "[t]he hybrid progeny of corn plant I026458, and progeny plants of subsequent generations, are essential to operate the claimed method." As we understand the examiner's argument, not only does appellant have to provide a written description of the starting corn plant (I026458), but appellant also must look into the future to determine every other potential corn plant that someone may wish to cross with the I026458 corn variety, and provide written descriptive support for not only every other corn plant that could be crossed with I026458, but also the resulting progeny of each cross.

As set forth in Reiffin, the purpose of the written description requirement is to "ensure that the scope of the right to exclude, as set forth in the claims does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification." Here the method of producing an inbred corn plant requires a plant of the corn variety I026458 be used as the starting material. To that end, to satisfy the written description requirement, the inventor

"must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention" [emphasis added]. Vas-Cath. The examiner has indicated that a claim to a plant of the corn variety I026458 is allowable, see e.g., appellant's claim 5. Therefore, in our opinion, there can be no doubt that appellant was in possession of a plant of the corn variety I026458, in addition to a method of using that plant to cross with any other corn plant to produce an inbred corn plant as set forth in appellant's claim 31.

In our opinion, it matters not what the other corn plants are, or what the progeny of a cross between corn variety I026458 and some other corn plant represents. As the examiner explains (Answer, page 20), patentability of the method of claim 31 "does not lie in the method steps, which require the simple acts of crossing corn plants, allowing progeny seed to be produced, and growing progeny plants from the seed...." In our opinion, patentability of the method of claim 31 does not lie in the various other or second corn plants either. In our opinion, patentability of the method of claim 31 lies in the use of the corn variety I026458. Accordingly, for the foregoing reasons, it is our opinion that appellant has "convey[ed] with reasonable clarity to those skilled in the art that, as of the filing date sought, [they were] in possession of the invention," Vas-Cath (emphasis omitted).

Summary

For the foregoing reasons, we reverse the rejection of claims 6, 11, 24, 25 and 27-31 under the written description provision of 35 U.S.C. § 112, first paragraph.

Enablement:

Claims 27-30 stand rejected under the enablement provision of 35 U.S.C. § 112, first paragraph. The examiner finds (Answer, page 41), claims 27-30 "are broadly drawn towards inbred corn plant I026458 further defined as having a genome comprising any single locus conversion, encoding any trait; or wherein the single locus was stably inserted into a corn genome by transformation." The examiner presents several lines of argument under this heading. We take each in turn.

I. Retaining all the morphological and physiological traits of I026458:

According to the examiner (Answer, page 41, emphasis added), appellant's specification "does not teach any I026458 plants comprising a single locus conversion produced by backcrossing, wherein the resultant plant retains all of its morphological and physiological traits in addition to exhibiting the single trait conferred by the introduced single locus. With reference to Hunsperger, Kraft, and Eshed the examiner asserts (Answer, bridging sentence, pages 44-45), "[t]he rejection raises the issue of how linkage drag hampers the insertion of single genes alone into a plant by backcrossing, while recovering all of the original plant's genome."

We note, however, that claims 27-30 do not require that the single locus conversion plant retain all of the morphological and physiological traits of the parent plant in addition to exhibiting the single trait conferred by the introduction of the single loci. Nor do claims 27-30 require that the resultant plant retain all of the original plant's genome in addition to the single locus transferred into the inbred via the backcrossing technique. As appellant explains (specification, page 30, emphasis added),

> [t]he term single locus converted plant as used herein refers to those corn plants which are developed by a plant breeding technique called backcrossing wherein essentially all of the desired morphological and physiological characteristics of an inbred are recovered in addition to the single locus transferred into the inbred via the backcrossing technique.

See also appellant's definition of single locus converted (conversion) plant at page 23 of the specification. We find nothing in the appellant's specification to indicate that the single locus converted plant retains all of the morphological and physiological traits, or all of the genome, of the parent plant in addition to the single locus transferred via the backcrossing technique. Accordingly, we disagree with the examiner's construction of claims 27-30 as "directed to exactly plant I026458 further comprising the single locus," which appears to disregard appellant's definition of a single locus converted plant. See Answer, page 46, emphasis added.

The examiner appears to appreciate (Answer, page 46) that appellant's specification provides an example of a converted plant. See e.g., specification, pages 35-36. However, for the foregoing reasons, we are not persuaded by the

examiner's assertion (Answer, page 46) that the specification provides "no indication that all of the morphological and physiological traits of [this converted] ... corn plant were recovered, and that only one single locus was transferred from the donor plant." To the contrary, the examiner provides no evidence that the converted plant exemplified in appellant's specification did not retain essentially all of the desired morphological and physiological characteristics of the inbred in addition to the characteristics conferred by the single locus transferred into the inbred via the backcrossing technique.

Further, we recognize appellant's argument (Brief, page 29) that the examiner failed to establish a nexus between Hunsperger's discussion of petunias; Kraft's discussion of sugar beets; and Eshed's discussion of tomatoes, and the subject matter of the instant application - corn. Absent evidence to the contrary, we agree with appellant (id.), "[t]he [examiner's] indication[19] that the references concerning petunias, sugar beets and tomatoes apply to corn is made without any support." That the examiner has failed to identify (Answer, page 45) an example "in the prior art of plants in which linkage drag does not occur," does not mean that linkage drag is expected to occur in corn breeding, which according to appellant (Reply Brief, page 11) "is extremely advanced and well known in the art...." In this regard, we agree with appellant (Brief, page 30; Accord Reply Brief, page 11), the examiner has improperly placed the burden on appellant to demonstrate that the examiner's unsupported assertion is not true.

[19] See Answer page 45, wherein the examiner asserts "[l]inkage drag appears to be a phenomenon that occurs in all plant types."

We remind the examiner, as set forth in In re Wright, 999 F.2d 1557, 1561-62, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993):

> When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement.

II. What plant is transformed in claim 28?

We recognize the examiner's assertion (Answer, page 43) that while claim 28 requires that a single locus be stably inserted into a corn genome by transformation, the claim does not indicate whether (1) the I026458 plant was transformed with the single locus, or (2) some other corn plant was transformed with the single locus and then introduced into I026458 by crossing. However, as appellant points out (Brief, page 11), claim 28 "specifies that the single locus was stably inserted into a corn genome. Loci that are stably inserted into a corn genome are also stably inherited. Thus the single locus need not have been inserted into the genome of corn variety I026458." Accordingly, the I026458 plant may be transformed with the single locus, or another plant may be transformed with the single locus and then introduced into I026458 by crossing.

It may be that the examiner is concerned that by transforming a non-I026458 plant with a single locus and then introducing this locus into I026458 by crossing would result in a plant that does not retain all of the morphological and

physiological traits, or all of the genome, of the I026458 plant. For the foregoing reasons, however, this line of reasoning is not persuasive.

III. The single locus to be introduced:

The examiner finds (Answer, page 43), "the claims do not place any limit on the single locus to be introduced" into I026458 plants. The examiner recognizes, however, that "[t]he prior art shows that hundreds of nucleotide sequences encoding products that confer various types of plant traits have been isolated at the time the instant invention was filed." Id. In addition, the examiner recognizes (id.), "[o]ne skilled in the art can transform any of these isolated nucleotide sequences known in the prior art into a corn plant cell, and regenerate a transgenic plant from the transformed cell."

Nevertheless, the examiner finds (Answer, bridging sentence, pages 43-44), "[u]ndue experimentation would be required by one skilled in the art to isolate single loci that govern the traits encompassed by the claims." In this regard, the examiner asserts (Answer, page 45) that the claims broadly encompass corn plants comprising any type of single loci, including those that have not yet been identified or isolated. To the extent that the examiner is asserting that appellant has not provided an enabling disclosure of single loci that have not been identified, we note that enablement under 35 U.S.C. § 112, first paragraph is evaluated as of appellant's filing date. As set forth in Chiron Corp. v. Genentech Inc., 363 F.3d 1247, 1254, 70 USPQ2d 1321, 1325-26 (Fed. Cir. 2004), "a patent document cannot enable technology that arises after the date of application. The law does not expect an applicant to disclose knowledge

invented or developed after the filing date. Such disclosure would be impossible. See In re Hogan, 559 F.2d 595, 605-06 [194 USPQ 527] (CCPA 1977)."

The examiner's comment, however, may be directed to his assertion (Answer, page 43) that "isolated loci whose products confer yield enhancement or enhanced yield stability (recited in claim 30), are not known in the prior art." However, as discussed, supra, it appears that contrary to the examiner's assertion a single locus that confers the trait of, for example, yield enhancement was known in the art prior to the filing date of the instant invention. In addition, as discussed, supra, appellant's specification asserts that such traits were known in the art. See specification, page 31. Accordingly, as set forth in In re Marzocchi, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971), the burden is on

> the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure.

On this record, we find only the examiner's unsupported conclusions as to why the specification does not enable the claimed invention. We remind the examiner that nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples. Marzocchi, 439 F.2d at 223, 169 USPQ at 369. In the absence of an evidentiary basis to support the rejection, the examiner has not sustained his initial burden of establishing a prima facie case of non-enablement.

In this regard, we note that the burden of proof does not shift to appellant until the examiner first meets his burden. Marzocchi, 439 F.2d at 223-224, 169 USPQ at 369-370.

We also recognize the examiner's assertion (Answer, page 44) that claims 27-29 "encompass plants with single loci whose functions are unknown ... [or where] the effects of expression of the single locus on the traits expressed by I026458 are unknown." While this may be true, the examiner has not provided any evidence to suggest that it would require undue experimentation to obtain a single locus converted plant wherein essentially all of the desired morphological and physiological characteristics of an inbred are recovered in addition to the characteristics conferred by the single locus transferred into the inbred via the backcrossing technique. See specification, page 23.

While it is not expressly stated in the text of the examiner's rejection, it may be that the examiner is concerned that the claims include inoperative embodiments. If so, the examiner is directed to Atlas Powder Co. v. E.I. DuPont De Nemours & Co., 750 F.2d 1569, 1576-77, 224 USPQ 409, 414 (Fed. Cir. 1984):

> Even if some of the claimed combinations were inoperative, the claims are not necessarily invalid. "It is not a function of the claims to specifically exclude ... possible inoperative substances...." In re Dinh-Nguyen, 492 F.2d 856, 859-59, 181 USPQ 46, 48 (CCPA 1974)(emphasis omitted). Accord, In re Geerdes, 491 F.2d 1260, 1265, 180 USPQ 789, 793 (CCPA 1974); In re Anderson, 471 F.2d 1237, 1242, 176 USPQ 331, 334-35 (CCPA 1971). Of course, if the number of inoperative combinations becomes significant, and in effect forces one of ordinary skill in the art to experiment unduly in order to practice the claimed invention, the claims might indeed be

invalid. *See* e.g., In re Cook, 439 F.2d 730, 735, 169 USPQ 298, 302 (CCPA 1971).

On this record, the examiner provides no evidence that the number of inoperative embodiments is so large that a person of ordinary skill in the art would have to experiment unduly to practice the claimed invention. To the contrary, the examiner recognizes (Answer, page 43) that "[t]he prior art shows that hundreds of nucleotide sequences encoding products that confer various types of plant traits have been isolated at the time the instant invention was filed"; and that "[o]ne skilled in the art can transform any of these isolated nucleotide sequences known in the prior art into a corn plant cell, and regenerate a transgenic plant from the transformed cell." Accordingly, we are not persuaded by the examiner's unsupported assertions.

For the foregoing reasons, we reverse the rejection of claims 27-30 under the enablement provision of 35 U.S.C. § 112, first paragraph.

SUMMARY

We reverse the rejection of claims 3, 6, 11, 14-20, and 27-30 under 35 U.S.C. § 112, second paragraph.

We reverse the rejection of claims 6, 11, 24, 25 and 27-31 under the written description provision of 35 U.S.C. § 112, first paragraph.

We reverse the rejection of claims 27-30 under the enablement provision of 35 U.S.C. § 112, first paragraph.

For the reasons set forth in n. 5 infra, we have not considered the merits of the rejection of claim 26 under the written description provision of 35 U.S.C. § 112, first paragraph.

REVERSED

Toni R. Scheiner Administrative Patent Judge	
Donald E. Adams Administrative Patent Judge	BOARD OF PATENT APPEALS AND INTERFERENCES
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The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte Thomas B. Carlson

Appeal No. 2004-2317[1]
Application No. 09/771,938

Heard: February 10, 2005[2]

Before SCHEINER, ADAMS and GREEN, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 3, 6, 11, 14-20, 24, 25, and 27-31. The examiner has indicated that claims 1, 2, 5, 7-10, 12, 13 and 21-23 are allowable. Answer, page 2. Claims 4 and 26 are cancelled. Brief, page 2.

[1] This appeal is substantially similar to Appeal No. 2004-1503, Application No. 09/606,808; Appeal No. 2004-1506, Application No. 09/771,938; Appeal No. 2004-1968, Application No. 10/00,0311; Appeal No. 2004-2343, Application No. 09/772,520; and Appeal No. 2005-0396, Application No. 10/077,589, which all share the same assignee, Monsanto Company, the parent of wholly-owned subsidiary DeKalb Genetics Corporation. Accordingly we have considered these appeals together.

[2] We note that examiner Ashwin Meta presented arguments at the oral hearing.

Claims 3, 6, 15, 16, 17, 27, 28, 30 and 31 are illustrative of the subject matter on appeal and are reproduced below. In addition, for convenience, we have reproduced allowable claims 2 and 5 below:

2. A population of seed of the corn variety I015036, wherein a sample of the seed of the corn variety I015036 was deposited under ATCC Accession No. PTA-3225.

3. The population of seed of claim 2, further defined as an essentially homogeneous population of seed.

5. A corn plant produced by growing a seed of the corn variety I015036, wherein a sample of the seed of the corn variety I015036 was deposited under ATCC Accession No. PTA-3225.

6. The corn plant of claim 5, having:
   (a) an SSR profile in accordance with the profile shown in Table 6; or
   (b) an isozyme typing profile in accordance with the profile shown in Table 7.

15. A corn plant capable of expressing all the physiological and morphological characteristics of the corn variety I015036, wherein a sample of the seed of the corn variety I015036 was deposited under ATCC Accession No. PTA-3225.

16. The corn plant of claim 15, further comprising a nuclear or cytoplasmic gene conferring male sterility.

17. A tissue culture of regenerable cells of a plant of corn variety I015036, wherein the tissue is capable of regenerating plants capable of expressing all the physiological and morphological characteristics of the corn variety I015036, wherein a sample of the seed of the corn variety I015036 was deposited under ATCC Accession No. PTA-3225.

27. The corn plant of claim 5, further defined as having a genome comprising a single locus conversion.

28. The corn plant of claim 27, wherein the single locus was stably inserted into a corn genome by transformation.

30. The corn plant of claim 27, wherein the locus confers a trait selected from the group consisting of herbicide tolerance; insect resistance; resistance to bacterial, fungal, nematode or viral disease; yield enhancement; waxy

starch; improved nutritional quality; enhanced yield stability; male sterility and restoration of male fertility.

31. A method of producing an inbred corn plant derived from the corn variety I015036, the method comprising the steps of:

(a) preparing a progeny plant derived from the corn variety I015036 by crossing a plant of the corn variety I015036 with a second corn plant, wherein a sample of the seed of the corn variety I015036 was deposited under ATCC Accession No. PTA-3225;
(b) crossing the progeny plant with itself or a second plant to produce a seed of a progeny plant of a subsequent generation;
(c) growing a progeny plant of a subsequent generation from said seed and crossing the progeny plant of a subsequent generation with itself or a second plant;
(d) repeating steps (b) and (c) for an addition[al] 3-10 generations to produce an inbred corn plant derived from the corn variety I015036.

The references relied upon by the examiner are:

Hunsperger et al. (Hunsperger)	5,523,520	Jun. 4, 1996

Eshed et al. (Eshed), "Less-Than-Additive Epistatic Interactions of Quantitative Trait Loci in Tomato," Genetics, Vol. 143, pp. 1807-17 (1996)

Kraft et al. (Kraft), "Linkage Disequilibrium and Fingerprinting in Sugar Beet," Theoretical and Applied Genetics, Vol. 101, pp. 323-36 (2000)

GROUNDS OF REJECTION

Claim 3 stands rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrase "an essentially homogeneous population of seed."

Claim 14 stands rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrase "[a]n essentially homogeneous population of corn plants produced by growing the seed of the corn variety I015036."

Claims 6 and 11 stand rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrase "in accordance with."

Claims 15, and 17-20[3] stand rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrase "capable of expressing."

Claims 16 and 27-30[4] stand rejected under 35 U.S.C. § 112, second paragraph as failing to limit the scope of the claims from which they depend.

Claim 28 stands rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of "the article 'a' in the recitation 'wherein the single locus was stably inserted into a corn genome.'"

Claim 30 stands rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrases "yield enhancement," "improved nutritional quality," and "enhanced yield stability."

Claims 6, 11, 24, 25 and 27-31 stand rejected under the written description provision of 35 U.S.C. § 112, first paragraph.

Claims 27-30 stand rejected under the enablement provision of 35 U.S.C. § 112, first paragraph.

We reverse.

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[3] According to the examiner (Answer, page 13), since claim 18 depends from claims 17 it is included in this rejection. We also note, while the examiner lists (Answer, page 4) claim 19 as rejected under 35 U.S.C. § 112, second paragraph, the examiner fails to explain the basis of this rejection. Accordingly, we assume since claim 19 ultimately depends from claim 17, claim 19, like claim 18, was intended to be included in this rejection.

[4] According to the examiner (Answer, page 4), "[c]laims ... 27-30 ... stand rejected under 35 U.S.C. [§] 112, second paragraph..." The examiner, however, provides no explanation as to why claim 29 is rejected. We can only assume that since claim 29, as well as claims 28 and 30, each depend from claim 27, they are rejected for the same reason as claim 27. Accordingly, we have included claims 28-30 with this ground of rejection.

BACKGROUND

The present "invention relates to inbred corn seed and plants of the variety designated I015036, and derivatives and tissue cultures thereof." Specification, page 1. According to appellant (specification, page 27), "[a] description of the physiological and morphological characteristics of corn plant I015036 is presented in Table 3" of the specification, pages 27-29. On this record the examiner has indicated that claims drawn to plants, plant parts, and seed of the corn variety designated I015036 are allowable. See e.g., claims 1, 2, 5, 7-10, 12 and 13, and Answer, page 2, wherein the examiner states "[c]laims 1, 2, 5, 7-10, 12 [and] 13 ... are allowed."

A second aspect of the present invention comprises hybrid plants and processes "for producing [first generation (F_1) hybrid[5]] corn seeds or plants, which ... generally comprise crossing a first parent corn plant with a second parent corn plant, wherein at least one of the first or second parent corn plants is a plant of the variety designated I015036." Specification, pages 7-9. On this record the examiner has indicated that claims drawn to a process of producing corn seed wherein the process comprises crossing a first parent corn plant with a second parent corn plant are allowable. See e.g., claims 21-23 and Answer, page 2, wherein the examiner states claims "21-23 are allowed."

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[5] According to the specification (page 21), a F_1 hybrid is "[t]he first generation progeny of the cross of two plants." During oral hearing, appellant confirmed that all claims drawn to hybrid plants or hybrid seeds (see e.g., claims 24 and 25) refer to F_1 hybrids.

A third aspect of the present invention comprises single locus converted plants of the corn variety I015036. Specification, page 6. As appellant explains (specification, page 23, emphasis added), single locus converted (conversion) plants are those plants

> which are developed by a plant breeding technique called backcrossing wherein <u>essentially</u> <u>all</u> of the desired morphological and physiological characteristics of an inbred are recovered in addition to the characteristics conferred by the single locus transferred into the inbred <u>via</u> the backcrossing technique. A single locus may comprise one gene, or in the case of transgenic plants, one or more transgenes integrated into the host genome at a single site (locus).

As appellant explains (specification, page 31):

> Many single locus traits have been identified that are not regularly selected for in the development of a new inbred but that can be improved by backcrossing techniques. Single locus traits may or may not be transgenic; examples of these traits include, but are not limited to, male sterility, waxy starch, herbicide resistance, resistance for bacterial, fungal, or viral disease, insect resistance, male fertility, enhanced nutritional quality, industrial usage, yield stability, and yield enhancement. These genes are generally inherited through the nucleus, but may be inherited through the cytoplasm. Some known exceptions to this are genes for male sterility, some of which are inherited cytoplasmically, but still act as single locus traits.

A final aspect of the present invention is directed to a process of producing an inbred corn plant <u>derived</u> from a plant of the corn variety I015036. <u>See</u> <u>e.g.</u>, claim 31. According to appellant's specification (bridging paragraph, pages 10-11),

> the present invention provides a method of producing an inbred corn plant derived from the corn variety I015036, the method comprising the steps of: (a) preparing a progeny plant derived from corn variety I015036, wherein said preparing comprises crossing a plant of the corn variety I015036 with a second corn plant, and

> wherein a sample of the seed of corn variety I015036 has been deposited under ATCC Accession No. ... [PTA-3225]; (b) crossing the progeny plant with itself or a second plant to produce a seed of a progeny plant of a subsequent generation; (c) growing a progeny plant of a subsequent generation from said seed of a progeny plant of a subsequent generation and crossing the progeny plant of a subsequent generation with itself or a second plant; and (d) repeating steps (c) and (d) for an addition 3-10 generations to produce an inbred corn plant derived from the corn variety I015036. In the method, it may be desirable to select particular plants resulting from step (c) for continued crossing according to steps (b) and (c). By selecting plants having one or more desirable traits, an inbred corn plant derived from the corn variety I015036 is obtained which possesses some of the desirable traits of corn variety I015036 as well potentially other selected traits.

According to the examiner (Answer, page 36), "[t]he patentability of the method of claim 31 does not lie in the method steps, which require the simple acts of crossing corn plants, allowing progeny seed to be produced, and growing progeny plants from the seed...." Therefore, as we understand this aspect of the claimed invention (e.g., claim 31), the intent is not to claim a specific inbred corn plant resulting from the claimed process. See claim 31. Instead, as we understand it, claim 31 is drawn to a process wherein an inbred corn plant is derived from the corn variety I015036.

As appellant explains (specification, page 3),

> The development of uniform corn plant hybrids requires the development of homozygous inbred plants, the crossing of these inbred plants, and the evaluation of the crosses. Pedigree breeding and recurrent selection are examples of breeding methods used to develop inbred plants from breeding populations. Those breeding methods combine the genetic backgrounds from two or more inbred plants or various other broad-based sources into breeding pools from which new inbred plants are developed by selfing and selection of desired phenotypes. The new inbreds are crossed with other inbred plants and the hybrids from these crosses are evaluated to determine which of those have commercial potential.

We emphasize, that while "new inbreds" having commercial potential may result from the method set forth in claim 31, the claim does not encompass any specific plant that is produced as a result of the method. Rather the claim encompasses only a method of producing an inbred corn plant that is "derived" from the corn variety I015036. The examiner has indicated that a claim drawn to a corn plant of the corn variety I015036 is allowable. See e.g., claim 5, and Answer, page 2, wherein the examiner states that claim 5 is allowed.

Against this backdrop, we now consider the rejections of record.

DISCUSSION

Definiteness:

Claims 3, 6, 11, 14-20 and 27-30 stand rejected under 35 U.S.C. § 112, second paragraph. For the following reasons we reverse.

Claim 3

Claim 3 depends from independent claim 2, and stands rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrase "an essentially homogeneous population of seed...." Answer, bridging paragraph, pages 4-5. According to the examiner (Answer, page 4), claim 2 is drawn to "'[a] population of seed of the corn variety I015036, wherein a sample of the seed of the corn variety I015036 was deposited under ATCC Accession No. PTA-3225." Thus, the examiner finds (Answer, page 5), the population of seed set forth in claim 2 "is a homogeneous population of seed of corn variety I015036."

Accordingly, the examiner finds (id.), "[t]he recitation, 'essentially homogeneous,' in claim 3 ... appear[s] to be superfluous."

However, as disclosed in appellant's specification (page 5),

> [e]ssentially homogeneous populations of inbred seed are those that consist essentially of the particular inbred seed, and are generally free from substantial numbers of other seed, so that the inbred seed forms between about 90% and about 100% of the total seed, and preferably, between about 95% and about 100% of the total seed.

Accordingly, we disagree with the examiner's assertion (Answer, page 6) that claim 3 is unclear simply because it may contain seed other than the seed of the corn variety I015036. We remind the examiner that claim language must be analyzed "not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary skill in the pertinent art." In re Moore, 439 F.2d 1232, 1235, 169 USPQ 236, 238 (CCPA 1971). Here, notwithstanding appellant's comments[6], it is our opinion that a person of ordinary skill in the art would recognize that an essentially homogeneous population of seed of the corn variety I015036 is a population of seed that is generally free from substantial numbers of other seed, e.g., wherein corn variety I015036 seed forms between about 90% and about 100% of the total seed in the population.[7]

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[6] According to appellant (Brief, page 7), an essentially homogeneous population of seed, is a population of seed that could be of non-uniform size and shape.

[7] Cf. the examiner's statement (Answer, page 6), "amending claim 3 to read '[a]n essentially homogeneous population of corn seeds consisting essentially of seed of claim 1', would obviate this rejection."

Accordingly, we reverse the rejection of claim 3 under 35 U.S.C. § 112, second paragraph.

Claim 14

Claim 14 stands rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrase "[a]n essentially homogeneous population of corn plants produced by growing the seed of the corn variety I015036." Answer, page 6. According to the examiner (Answer, bridging paragraph, pages 6-7), "[t]he I015036 seed can only produce I015036 plants. ... [Therefore,] [t]he population can ... only consist of I015036 plants." Accordingly, the examiner finds it unclear "why the population is referred to as 'essentially homogeneous,' since such populations can comprise more than one variety of plant." Answer, page 7.

As appellant discloses (specification, page 6), "[t]he population of inbred corn seed of the invention can further be particularly defined as being essentially free from hybrid seed. The inbred seed population may be separately grown to provide an essentially homogeneous population of inbred corn plants designated I015036." As we understand the claim, growing the seed of claim 3, for example, would produce an essentially homogeneous population of corn plants of the corn variety I015036.[8]

[8] Cf. The examiner's statement (Answer, page 8), amending claim 14 "to read, '[a]n essentially homogeneous population of corn plants produced by growing a population of corn seed consisting essentially of the seed of corn plant I015036...' would obviate the rejection."

In addition, we direct the examiner's attention to Appeal No. 2005-0396, wherein a claim similar to claim 14 was presented for our review. In Appeal No. 2005-0396, the examiner of record indicated that claim 14, directed to "[a]n essentially homogeneous population of corn plants produced by growing the seed of the corn variety I180580...." was allowable. Accordingly, we find that the examiner has treated claim 14 in a manner that is inconsistent with the prosecution of claim 14 in 2005-0396. As we understand it, the only difference between claim 14 as it appears in Appeal No. 2005-0396 and the instant appeal is the variety of corn seed from which the plant is produced.

Accordingly we reverse the rejection of claim 14 under 35 U.S.C. § 112, second paragraph.

Claims 6 and 11

Claims 6 and 11 stand rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrase "in accordance with." According to the examiner (Answer, page 9), it is unclear if a plant "that generally follows the trend of the profile of Table 6, but which differs at one or a few loci, [would] be considered in 'conformity' or 'in accordance' with the profile of Table 6."

On this record, we understand the phrase "in accordance with" as it is used in claims 6 and 11 to mean "the same"[9]. Stated differently, we understand the claims to read:

6. The corn plant of claim 5, having:
   (a) the same SSR profile as shown in Table 6; or

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[9] During the February 10, 2005 oral hearing appellant's representative confirmed that the phrase "in accordance with" was intended to mean "the same."

(b) the same isozyme typing profile as shown in Table 7.

11. The plant part of claim 10, wherein said cell is further defined as having:
   (a) The same SSR profile as shown in Table 6; or
   (b) The same isozyme typing profile as shown in Table 7.

Accordingly we reverse the rejection of claims 6 and 11 under 35 U.S.C. § 112, second paragraph.

Claims 15 and 17-20

Claims 15, and 17-20 stand rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrase "capable of expressing," or "capable of regenerating." According to the examiner (Answer, page 11), the claims do "not make clear if the plant actually expresses the traits, or when or under what conditions the traits are expressed." In this regard, the examiner finds (Answer, page 12),

> while the plant has the capacity to express the characteristics, for some reason it may not. Certain characteristics of a plant are expressed only at certain times of its life cycle, and are incapable of being expressed at other times. The colors of flower parts such as silks, or fruit parts such as husks, are examples. The promoters of many genes conferring traits require a transcription factor to become active. Is a plant that has such a gene, but not the transcription factor, considered "capable of expressing" that gene, and the trait associated with that gene, and is such a plant encompassed by the claims?

To address the examiner's concerns, we find it sufficient to state that if a plant has the capacity to express the claimed characteristics it meets the requirement of the claim regarding "capable of," notwithstanding that due to a particular phase of the life cycle the plant is not currently expressing a particular characteristic. Alternatively, if a plant is incapable of expressing the claimed

characteristics at any phase of the life cycle, because it lacks, for example, the "transcription factor" required for expression – such a plant would not meet the requirement of the claim regarding "capable of."

Here, we find the examiner's extremely technical criticism to be a departure from the legally correct standard of considering the claimed invention from the perspective of one possessing ordinary skill in the art.[10] In our opinion, a person of ordinary skill in the art would understand what is claimed. Amgen Inc. v. Chugai Pharmaceutical Co., Ltd., 927 F.2d 1200, 1217, 18 USPQ2d 1016, 1030 (Fed. Cir. 1991). We find the same to be true for the phrase "capable of" as set forth in claims 17-20.

Accordingly we reverse the rejection of claims 15, and 17-20 under 35 U.S.C. § 112, second paragraph.

Claims 16 and 27-30

Claims 16 and 27-30 stand rejected under 35 U.S.C. § 112, second paragraph as failing to limit the scope of the claims from which they depend. According to the examiner (Answer, page 9), since the plant set forth in claim 16 is male sterile it cannot express all the morphological and physiological characteristics of the male fertile corn variety I015036. Similarly, the examiner finds it unclear whether the plant set forth in claim 27 has all the characteristics of the plant set forth in claim 5, from which claim 27 depends. Id. In response,

[10] Cf. Digital Equipment Corp. v. Diamond, 653 F.2d 701, 724, 210 USPQ 521, 546 (CA 1981).

appellant asserts (Brief, bridging paragraph, pages 8-9), claims 16 and 27 simply add a further limitation to the claims from which they depend. We agree.

For example, claim 16 reads on a corn plant capable of expressing all the physiological and morphological characteristics of the corn variety I015036, further comprising a nuclear or cytoplasmic gene conferring male sterility. In our opinion, the claims reasonably apprise those of skill in the art of their scope. Amgen. As set forth in Shatterproof Glass Corp. v. Libbey-Owens Ford Co., 758 F.2d 613, 624, 225 USPQ 634, 641 (Fed. Cir. 1985), "[i]f the claims, read in the light of the specifications, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, the courts can demand no more."

Accordingly we reverse the rejection of claims 16 and 27-30 under 35 U.S.C. § 112, second paragraph.

Claim 28

Claim 28 stands rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of "the article 'a' in the recitation 'wherein the single locus was stably inserted into a corn genome.'" According to the examiner (Answer, page 13), "[t]he recitation does not make clear if the genome is that of I015036 or that of a different corn plant."

According to appellant's specification (page 23, emphasis removed), a "Single Locus Converted (Conversion) Plant" refers to

> [p]lants which are developed by a plant breeding technique called backcrossing wherein essentially all of the desired morphological and physiological characteristics of an inbred are recovered in

> addition to the characteristics conferred by the single locus transferred into the inbred via the backcrossing technique. A single locus may comprise one gene, or in the case of transgenic plants, one or more transgenes integrated into the host genome at a single site (locus).

Accordingly, we agree with appellant (Brief, page 10) "[t]he single locus referred to in claim 28 may or may not have been directly inserted into the genome of the claimed plant." As we understand the claim, and arguments of record, claim 28 presents two possibilities: (1) the single locus is directly inserted into the claimed plant and nothing further need be done; or (2) the single locus is directly inserted into a different plant, which is then used to transfer the single locus to the claimed plant through use of the plant breeding technique known as backcrossing.

In our opinion, the claim reasonably apprises those of skill in the art of its scope. Amgen. Accordingly, we reverse the rejection of claim 28 under 35 U.S.C. § 112, second paragraph.

Claim 30

Claim 30 stands rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrases "yield enhancement," "improved nutritional quality," and "enhanced yield stability." According to the examiner the terms "yield enhancement," "improved nutritional quality," and "enhanced yield stability" are relative and have no definite meaning. Answer, page 14. The examiner is correct (Answer, page 14), when a word of degree is used appellant's specification must provide some standard for measuring that degree.

Seattle Box. Co. v. Industrial Crating & Packing, Inc., 731 F.2d 818, 826, 221 USPQ 568, 573-574 (Fed. Cir. 1984).

On this record, appellant asserts (Brief, page 11), it is "understood the enhancement of yield or yield stability and improved nutritional quality is relative to a plant lacking the single locus. The metes and bounds of the claim are thus fully understood by one of skill in the art and the use of the terms is not indefinite." On reflection, we agree with appellant. The fact that some claim language is not mathematically precise does not per se render the claim indefinite. Seattle Box. As set forth in Shatterproof Glass, "[i]f the claims, read in the light of the specifications, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, the courts can demand no more." In our opinion, a person of ordinary skill in the art would have understood the enhancement of yield or yield stability and improved nutritional quality is relative to a plant lacking the single locus.

Accordingly we reverse the rejection of claim 30 under 35 U.S.C. § 112, second paragraph.

Written Description:

Claims 6, 11, 24, 25 and 27-31 stand rejected under 35 U.S.C. § 112, first paragraph, as the specification fails to adequately describe the claimed invention. For the following reasons, we reverse.

Claims 24 and 25[11]

Claims 24 and 25 both depend from claim 23. On this record, the examiner has indicated that claim 23 is allowable. Answer, page 2. The examiner finds (Answer, page 16), claims 24 and 25 are drawn to a hybrid plant or seed "produced by crossing inbred corn plant I015036 with any second, distinct inbred corn plant."

As we understand it, based on this construction of claims 24 and 25, the examiner is of the opinion that since the hybrids inherit only ½ of their diploid[12] set of chromosomes from the plant of corn variety I015036, a person of skill in the art would not have viewed the teachings of the specification as sufficient to demonstrate that appellant was in possession of the genus of hybrid seeds and plants encompassed by claims 24 and 25. According to the examiner (Answer, page 22), "[t]he fact that any hybrid plant will inherit half of its alleles from I015036 then does not provide sufficient description of the morphological and physiological characteristics expressed by the claimed hybrid plants."

There is no doubt that the expressed gene products of a hybrid plant, e.g., the morphological and physiological traits, of I015036 and a non-I015036 corn plant will depend on the combination of the genetic material inherited from both parents. See Answer, page 23. Nevertheless, we disagree with the examiner's

[11] We recognize, as does the examiner (Answer, page 22) that appellant's reference to claims 22-26 (Brief, page 13) was intended to be a reference to claims 24 and 25.

[12] According to appellant's specification (page 21), diploid means "a cell or organism having two sets of chromosomes."

conclusion (id.) that "[t]he fact that any hybrid plant will inherit half of its alleles from I015036 then does not provide sufficient description of the morphological and physiological characteristics expressed by the claimed hybrid plants."

On these facts, we find it necessary to take a step back and consider what is claimed. The claims are drawn to a F_1 hybrid seed (claim 24) or plant (claim 25) resulting from a cross between a plant of corn variety I015036 and a non-I015036 corn variety. The claims do not require the hybrid to express any particular morphological or physiological characteristic. Nor do the claims require that a particular non-I015036 corn variety be used.[13] All that is required by the claims is that the hybrid has one parent that is a plant of corn variety I015036. Since the examiner has indicated that the seed and the plant of the corn variety I015036 are allowable (see claims 1 and 5), there can be no doubt that the specification provides an adequate written description of this corn variety. In addition, the examiner appears to recognize (Answer, page 25) that appellant's specification describes an exemplary hybrid wherein one parent was a plant of the corn variety I015036, see e.g., specification, pages 53-59. Accordingly, it is unclear to this merits panel what additional description is necessary.

As set forth in Reiffin v. Microsoft Corp., 214 F.3d 1342, 1345, 54 USPQ2d 1915, 1917 (Fed. Cir. 2000), the purpose of the written description

[13] According to appellant (Brief, page 15), "hundreds or even thousands of different inbred corn lines were well known to those of skill in the art prior to the filing [date] of the instant application, each of which could be crossed to make a hybrid plant with in the scope of the claims."

requirement is to "ensure that the scope of the right to exclude, as set forth in the claims does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification." Here the hybrid seed or plant has one parent that is a plant of the corn variety I015036. To that end, to satisfy the written description requirement, the inventor "must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention" [emphasis added]. Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). For the foregoing reasons it is our opinion that appellant has provided an adequate written description of the subject matter set forth in claims 24 and 25.

We recognize the examiner's argument relating to SSR and isozyme markers (Answer, pages 25-29), as well as the examiner's arguments concerning a correlation between the hybrid's genome structure and the function of the hybrid plant (Answer, pages 23-25). However, for the foregoing reasons, we are not persuaded by these arguments.

Claims 6 and 11

Claims 6 and 11 depend ultimately upon claim 5. On this record, the examiner has indicated that claim 5 is allowable. Answer, page 2.

According to the examiner (Answer, page 8), while the specification provides the locus names and allele numbers of the SSR markers, the specification does not provide the actual nucleotide sequences that make up the markers. According to the examiner (Answer, page 18), "names of loci alone do not describe the structures of the markers themselves. Without a description of

the sequences of the markers, one cannot confirm their presence." In response, appellant points out (Brief, page 26), "the SSR markers were from Celera AgGen, Inc., which provides a commercial service for genotyping of maize varieties." In other words, a person of ordinary skill in the art could use the commercially available service provided by Celera AgGen, Inc. to determine whether a corn plant produced by growing a seed of the corn variety I015036 has an SSR profile which is the same as that shown in Table 6. Therefore, it is unclear to this panel why the examiner believes that such a disclosure fails to provide adequate written descriptive support for the claimed invention.[14] Accordingly, we are not persuaded by the examiner's argument.

Regarding the isozyme typing profile, the examiner finds (Answer, page 18), "Table 7 provides names of loci where isozyme markers reside, for three different corn plants, and a numerical value that represents the numbers of alleles at isozyme loci types. The nucleotide sequences that make up these loci are not described." In response, appellant points out (Brief, page 26), the isozyme "markers are well known and isozyme analysis in general [is] very well known having been used for decades." In this regard, we remind the examiner that the inquiry into whether the description requirement is met must be determined on a case-by-case basis and is a question of fact. In re Wertheim, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976). A description as filed is

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[14] We are not persuaded by the examiner's assertion (Answer, page 28) "that the [commercially available] service used to detect SSR markers is currently available is not a guarantee that it will remain so for the life of a patent issuing from the application." Cf. In re Metcalfe, 410 F.2d 1378, 1382, 161 USPQ 789, 792-3 (CCPA 1969).

presumed to be adequate; unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption. See e.g., In re Marzocchi, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). The examiner, therefore, must have a reasonable basis to challenge the adequacy of the written description. Accordingly, it is the examiner who has the initial burden of establishing by a preponderance of evidence that a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. Wertheim, 541 F.2d at 263, 191 USPQ at 97. On this record, the examiner provides no evidence to support the assertion that simply because appellant has not provided the sequences that make up the loci for particular isozymes, appellant's specification does not adequately describe the claimed invention. Accordingly, we are not persuaded by the examiner's argument.

The examiner finds (Answer, page 37), claims 6 and 11 require that the claimed plant or plant cell exhibit either the claimed SSR profile or the isozyme profile. According to the examiner (id.), "[t]he genome of the cells of the I015036 seed deposited with the ATCC has both the SSR profile and the isozyme typing profile shown in Tables 5 and 6 for that plant. No plant is mentioned in the specification that has one genetic marker profile but not the other." The examiner's concern appears to be misplaced. To the extent that the examiner is concerned that the claim is open to read on a plant other than a corn plant produced by growing a seed of the corn variety I015036, we remind the

examiner that both claims 6 and 11 ultimately depend from claim 5[15], which is drawn to "[a] corn plant produced by growing a seed of the corn variety I015036...."

It appears that the examiner may have read claims 6 and 11 as drawn to a corn plant or plant cell having only one of the recited profiles. However, as we understand claims 6 and 11, determining whether the claimed corn plant (claim 6) or plant cell (claim 11) has one of the profiles does not mean that the plant, or plant cell would not also exhibit the other profile.

In addition, we direct the examiner's attention to claims 6 and 11 of Appeal No. 2005-0396. As we understand it, notwithstanding differences in the SSR and isozyme profiles, the disclosure in the specification as well as the language of the claims is substantially similar to that of the instant application. Nevertheless, the examiner in Appeal No. 2005-0396 apparently found that appellant's specification provided an adequate written description of the claimed invention as no rejection of claims 6 and 11 was made under the written description provision of 35 U.S.C. § 112, first paragraph in Appeal No. 2005-0396. Accordingly, we find that the examiner has treated claims 6 and 11 in a manner that is inconsistent with the prosecution of similar claims in related application 10/077,589, which is the subject matter of Appeal No. 2005-0396.

For the foregoing reasons, we are not persuaded by the examiner's arguments.

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[15] The examiner has indicated that claim 5 is allowable. Answer, page 2.

Claims 27-30

According to the examiner (Answer, page 18), "[c]laims 27-30 are drawn towards I015036 plants further comprising a single locus conversion, or wherein the single locus was stably inserted into a corn genome by transformation." The examiner finds, however, that "the specification does not describe identified or isolated single loci for all corn plant traits." Answer, page 19. More specifically, the examiner finds (id.), claims 27-30 "broadly encompass single loci that have not been discovered or isolated." To the extent that the examiner is asserting that appellant has not provided an enabling disclosure of single loci that have not been identified, we note that to satisfy the written description requirement, the inventor "must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention" [emphasis added]. Vas-Cath.

Nevertheless, it may be that the examiner's concern (Answer, page 31), is that "single loci that alone govern 'yield enhancement' or 'enhanced yield stability' have not been discovered." In this regard, the examiner asserts (Answer, page 32), "the references cited in the specification do not describe isolated single genes or loci that confer yield enhancement or yield stability." Therefore, the examiner concludes (id.), "[a]ppellant cannot be in possession of plants further comprising single loci that have yet to be identified." The examiner, however, provides no evidence to support the assertion that a person of ordinary skill in the art would not recognize that single loci for yield enhancement or yield stability are known in the art. In this regard, we note that

appellant discloses (specification, page 31), "[m]any single locus traits have been identified ... examples of these traits include, but are not limited to, ... enhanced nutritional quality, industrial usage, yield stability, and yield enhancement." It appears that the examiner has overlooked appellant's assertion that single locus traits for yield stability and yield enhancement are well known in the art. To this end, we direct the examiner's attention to, for example, United States Patent No. 5,936,145 ('145)[16], issued August 10, 1999, which is prior to the filing date of the instant application. For clarity, we reproduce claims 8, 29 and 39 of the '145 patent below:

> 8. A corn plant having all the physiological and morphological characteristics of corn plant 87DIA4, a sample of the seed of said corn plant having been deposited under ATCC Accession No. 203192.
>
> 29. The corn plant of claim 8, further comprising a single gene conversion.
>
> 39. The single gene conversion of the corn plant of claim 29, where the gene confers enhanced yield stability.

As we understand it, claim 39 of the '145 patent, is drawn to a corn plant which comprises a single gene conversion, wherein the gene confers enhanced yield stability. Thus, contrary to the examiner's assertion it appears, for example, that a single gene that confers enhanced yield stability was known in the art prior to the filing date of the instant application. We remind the examiner "a patent need not teach, and preferably omits, what is well known in the art." Hybritech

[16] We note that the assignee of the '145 patent is DeKalb Genetics Corporation. The assignee of the present application is Monsanto Company, the parent of wholly-owned subsidiary DeKalb Genetics Corporation.

Incorporated v. Monoclonal Antibodies, Inc. 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986).

We remind the examiner that the inquiry into whether the description requirement is met must be determined on a case-by-case basis and is a question of fact. Wertheim, 541 F.2d at 262, 191 USPQ at 96. A description as filed is presumed to be adequate; unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption. See e.g., Marzocchi. The examiner, therefore, must have a reasonable basis to challenge the adequacy of the written description. Accordingly, it is the examiner who has the initial burden of establishing by a preponderance of evidence that a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. Wertheim, 541 F.2d at 263, 191 USPQ at 97. On this record, the examiner provides no evidence to support the assertion that single loci that govern, for example, yield enhancement or enhanced yield stability are not described.

For the foregoing reasons, we are not persuaded by the examiner's arguments.

Claim 31

Claim 31 is drawn to a method of producing an inbred corn plant derived from the corn variety I015036. The claimed method begins by crossing a plant of the corn variety I015036 with any other corn plant. The method requires that the progeny corn plant be crossed either to itself, or with any other corn plant, and that the progeny of this cross be further crossed to itself, or with another corn

plant, and so on throughout several generations. As we understand it, claim 31, in its simplest form, is directed to a method of using a plant of the corn variety I015036 to produce an inbred corn plant.

Nevertheless, the examiner finds (Answer, page 20), "[a] review of the claim indicates that hybrid progeny of corn plant I015036 are required to perform further crosses, and that progeny of subsequent generations can be further outcrossed with different corn plants." Therefore, the examiner concludes (id.), "[t]he hybrid progeny of corn plant I015036, and progeny plants of subsequent generations, are essential to operate the claimed method." As we understand the examiner's argument, not only does appellant have to provide a written description of the starting corn plant (I015036), but appellant also must look into the future to determine every other potential corn plant that someone may wish to cross with the I015036 corn variety, and provide written descriptive support for not only every other corn plant that could be crossed with I015036, but also the resulting progeny of each cross.

As set forth in Reiffin, the purpose of the written description requirement is to "ensure that the scope of the right to exclude, as set forth in the claims does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification." Here the method of producing an inbred corn plant requires a plant of the corn variety I015036 be used as the starting material. To that end, to satisfy the written description requirement, the inventor "must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention" [emphasis added].

Vas-Cath. The examiner has indicated that a claim to a plant of the corn variety I015036 is allowable, see e.g., appellant's claim 5. Therefore, in our opinion, there can be no doubt that appellant was in possession of a plant of the corn variety I015036, in addition to a method of using that plant to cross with any other corn plant to produce an inbred corn plant as set forth in appellant's claim 31.

In our opinion, it matters not what the other corn plants are, or what the progeny of a cross between corn variety I015036 and some other corn plant represents. As the examiner explains (Answer, bridging paragraph, pages 20-21), patentability of the method of claim 31 "does not lie in the method steps, which require the simple acts of crossing corn plants, allowing progeny seed to be produced, and growing progeny plants from the seed...." In our opinion, patentability of the method of claim 31 does not lie in the various other or second corn plants either. In our opinion, patentiblity of the method of claim 31 lies in the use of the corn variety I015036. Accordingly, for the foregoing reasons, it is our opinion that appellant has "convey[ed] with reasonable clarity to those skilled in the art that, as of the filing date sought, [they were] in possession of the invention," Vas-Cath (emphasis omitted).

Summary

For the foregoing reasons, we reverse the rejection of claims 6, 11, 24, 25 and 27-31 under the written description provision of 35 U.S.C. § 112, first paragraph.

Enablement:

Claims 27-30 stand rejected under the enablement provision of 35 U.S.C. § 112, first paragraph. The examiner finds (Answer, page 39), claims 27-30 "are broadly drawn towards inbred corn plant I015036 further defined as having a genome comprising any single locus conversion, encoding any trait; or wherein the single locus was stably inserted into a corn genome by transformation." The examiner presents several lines of argument under this heading. We take each in turn.

I. Retaining all the morphological and physiological traits of I015036:

According to the examiner (Answer, page 38, emphasis added), "the specification does not teach any I015036 plants comprising a single locus conversion produced by backcrossing, wherein the resultant plant retains all of its morphological and physiological traits in addition to exhibiting the single trait conferred by the introduced single locus." With reference to Hunsperger, Kraft, and Eshed the examiner asserts (Answer, page 41), "[t]he rejection raises the issue of how linkage drag hampers the insertion of single genes alone into a plant by backcrossing, while recovering all of the original plant's genome."

We note, however, that claims 27-30 do not require that the single locus conversion plant retain all of the morphological and physiological traits of the parent plant in addition to exhibiting the single trait conferred by the introduction of the single loci. Nor do claims 27-30 require that the resultant plant retain all of the original plant's genome in addition to the single locus transferred into the

inbred via the backcrossing technique. As appellant explains (specification, bridging paragraph, pages 29-30, emphasis added),

> [t]he term single locus converted plant as used herein refers to those corn plants which are developed by a plant breeding technique called backcrossing wherein essentially all of the desired morphological and physiological characteristics of an inbred are recovered in addition to the single locus transferred into the inbred via the backcrossing technique.

See also appellant's definition of single locus converted (conversion) plant at page 23 of the specification. We find nothing in the appellant's specification to indicate that the single locus converted plant retains all of the morphological and physiological traits, or all of the genome, of the parent plant in addition to the single locus transferred via the backcrossing technique. Accordingly, we disagree with the examiner's construction of claims 27-30 as "directed to exactly plant I015036, further comprising the single locus," which appears to disregard appellant's definition of a single locus converted plant. See Answer, page 43, emphasis added.

The examiner appears to appreciate (Answer, page 43) that appellant's specification provides an example of a converted plant. See e.g., specification, pages 35-36. However, for the foregoing reasons, we are not persuaded by the examiner's assertion (Answer, page 43) that the specification provides "no indication that all of the morphological and physiological traits of [this converted] ... corn plant were recovered, and that only one single locus was transferred from the donor plant." To the contrary, the examiner provides no evidence that the converted plant exemplified in appellant's specification did not retain

essentially all of the desired morphological and physiological characteristics of the inbred in addition to the characteristics conferred by the single locus transferred into the inbred via the backcrossing technique.

Further, we recognize appellant's argument (Brief, page 27) that the examiner failed to establish a nexus between Hunsperger's discussion of petunias; Kraft's discussion of sugar beets; and Eshed's discussion of tomatoes, and the subject matter of the instant application - corn. Absent evidence to the contrary, we agree with appellant (id.), the examiner's opinion[17] that the references concerning petunias, sugar beets and tomatoes apply to corn is unsupported on this record. That the examiner has failed to identify (Answer, page 41) an example "in the prior art of plants in which linkage drag does not occur," does not mean that linkage drag is expected to occur in corn breeding, which according to appellant (Reply Brief, page 10) "is extremely advanced and well known in the art...." In this regard, we agree with appellant (Brief, page 28; Accord Reply Brief, page 11), the examiner has improperly placed the burden on appellant to demonstrate that the examiner's unsupported assertion is not true. We remind the examiner, as set forth in In re Wright, 999 F.2d 1557, 1561-62, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993):

> When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for

[17] See Answer page 41, wherein the examiner asserts "[l]inkage drag appears to be a phenomenon that occurs in all plant types."

doubting any assertions in the specification as to the scope of enablement.

II. <u>What plant is transformed in claim 28</u>?

We recognize the examiner's assertion (Answer, page 39) that while claim 28 requires that a single locus be stably inserted into a corn genome by transformation, the claim does not indicate whether (1) the I015036 plant was transformed with the single locus, or (2) some other corn plant was transformed with the single locus and then introduced into I015036 by crossing. However, as appellant points out (Brief, page 12), claim 28 "specifies that the single locus was stably inserted into a corn genome. Loci that are stably inserted into a corn genome are also stably inherited. Thus the single locus need not have been inserted into the genome of corn variety I015036." Accordingly, the I015036 plant may be transformed with the single locus, or another plant may be transformed with the single locus and then introduced into I015036 by crossing.

It may be that the examiner is concerned that by transforming a non-I015036 plant with a single locus and then introducing this locus into I015036 by crossing would result in a plant that does not retain <u>all</u> of the morphological and physiological traits, or <u>all</u> of the genome, of the I015036 plant. For the foregoing reasons, however, this line of reasoning is not persuasive.

III. <u>The single locus to be introduced</u>:

The examiner finds (Answer, page 40), "the claims do not place any limit on the single locus to be introduced" into I015036 plants. The examiner recognizes, however, that "[t]he prior art shows that hundreds of nucleotide

sequences encoding products that confer various types of plant traits have been isolated at the time the instant invention was filed." Id. In addition, the examiner recognizes (id.), "[o]ne skilled in the art can transform any of these isolated nucleotide sequences known in the prior art into a corn plant cell, and regenerate a transgenic plant from the transformed cell."

Nevertheless, the examiner finds (id.), "[u]ndue experimentation would be required by one skilled in the art to isolate single loci that govern the traits encompassed by the claims." In this regard, the examiner asserts (Answer, page 44) that the claims broadly encompass corn plants comprising any type of single loci, including those that have not yet been identified or isolated. To the extent that the examiner is asserting that appellant has not provided an enabling disclosure of single loci that have not been identified, we note that enablement under 35 U.S.C. § 112, first paragraph is evaluated as of appellant's filing date. As set forth in Chiron Corp. v. Genentech Inc., 363 F.3d 1247, 1254, 70 USPQ2d 1321, 1325-26 (Fed. Cir. 2004), "a patent document cannot enable technology that arises after the date of application. The law does not expect an applicant to disclose knowledge invented or developed after the filing date. Such disclosure would be impossible. See In re Hogan, 559 F.2d 595, 605-06 [194 USPQ 527] (CCPA 1977)."

The examiner's comment, however, may be directed to his assertion (Answer, page 40) that "isolated loci whose products confer yield enhancement or enhanced yield stability (recited in claim 30), are not known in the prior art." However, as discussed, supra, it appears that contrary to the examiner's

assertion a single locus that confers the trait of, for example, yield enhancement was known in the art prior to the filing date of the instant invention. In addition, as discussed, supra, appellant's specification asserts that such traits were known in the art. See specification, page 31. Accordingly, as set forth in In re Marzocchi, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971), the burden is on

> the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure.

On this record, we find only the examiner's unsupported conclusions as to why the specification does not enable the claimed invention. We remind the examiner that nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples. Marzocchi, 439 F.2d at 223, 169 USPQ at 369. In the absence of an evidentiary basis to support the rejection, the examiner has not sustained his initial burden of establishing a prima facie case of non-enablement. In this regard, we note that the burden of proof does not shift to appellant until the examiner first meets his burden. Marzocchi, 439 F.2d at 223-224, 169 USPQ at 369-370.

We also recognize the examiner's assertion (Answer, pages 40-41) that claims 27-29 "encompass plants with single loci whose functions are unknown," or where the effects of expression of the single locus on the traits expressed by

1015036 are unknown. While this may be true, the examiner has not provided any evidence to suggest that it would require undue experimentation to obtain a single locus converted plant wherein essentially all of the desired morphological and physiological characteristics of an inbred are recovered in addition to the characteristics conferred by the single locus transferred into the inbred via the backcrossing technique. See specification, page 23.

While it is not expressly stated in the text of the examiner's rejection, it may be that the examiner is concerned that the claims include inoperative embodiments. If so, the examiner is directed to Atlas Powder Co. v. E.I. DuPont De Nemours & Co., 750 F.2d 1569, 1576-77, 224 USPQ 409, 414 (Fed. Cir. 1984):

> Even if some of the claimed combinations were inoperative, the claims are not necessarily invalid. "It is not a function of the claims to specifically exclude ... possible inoperative substances...." In re Dinh-Nguyen, 492 F.2d 856, 859-59, 181 USPQ 46, 48 (CCPA 1974)(emphasis omitted). Accord, In re Geerdes, 491 F.2d 1260, 1265, 180 USPQ 789, 793 (CCPA 1974); In re Anderson, 471 F.2d 1237, 1242, 176 USPQ 331, 334-35 (CCPA 1971). Of course, if the number of inoperative combinations becomes significant, and in effect forces one of ordinary skill in the art to experiment unduly in order to practice the claimed invention, the claims might indeed be invalid. See e.g., In re Cook, 439 F.2d 730, 735, 169 USPQ 298, 302 (CCPA 1971).

On this record, the examiner provides no evidence that the number of inoperative embodiments is so large that a person of ordinary skill in the art would have to experiment unduly to practice the claimed invention. To the contrary, the examiner recognizes (Answer, page 40) that "[t]he prior art shows that hundreds of nucleotide sequences encoding products that confer various

types of plant traits have been isolated at the time the instant invention was filed"; and that "[o]ne skilled in the art can transform any of these isolated nucleotide sequences known in the prior art into a corn plant cell, and regenerate a transgenic plant from the transformed cell." Accordingly, we are not persuaded by the examiner's unsupported assertions.

For the foregoing reasons, we reverse the rejection of claims 27-30 under the enablement provision of 35 U.S.C. § 112, first paragraph.

SUMMARY

We reverse the rejection of claims 3, 6, 11, 14-20, and 27-30 under 35 U.S.C. § 112, second paragraph.

We reverse the rejection of claims 6, 11, 24, 25 and 27-31 under the written description provision of 35 U.S.C. § 112, first paragraph.

We reverse the rejection of claims 27-30 under the enablement provision of 35 U.S.C. § 112, first paragraph.

REVERSED

Toni R. Scheiner
Administrative Patent Judge

Donald E. Adams
Administrative Patent Judge

Lora M. Green
Administrative Patent Judge

BOARD OF PATENT APPEALS AND INTERFERENCES

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Thomas B. Carlson

Serial No.: 09/771,938

Filed: January 29, 2001

For: PLANTS AND SEEDS OF CORN VARIETY I015036

Group Art Unit: 1638

Examiner: Mehta, Ashwin D.

Atty. Dkt. No.: DEKA:281US

CERTIFICATE OF MAILING
37 C.F.R. §1.8

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date below:

August 16, 2004
Date

Robert E. Hanson

REPLY BRIEF

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REPLY BRIEF

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Alexandria, VA 22313-1450

Sir:

Appellants hereby submit an original and two copies of this Reply Brief in response to the Examiner's Answer, dated June 16, 2004. A Request for Oral Argument and the corresponding fee are being filed concurrently. It is believed that no additional fees are due; however, should any other fees be due the Commissioner is authorized to withdraw the appropriate fees from Fulbright & Jaworski Deposit Account No. 50-1212/DEKA:281US.

Please date stamp and return the enclosed postcard to evidence receipt of this document.

I. REAL PARTIES IN INTEREST

The real party in interest is Monsanto Company, the parent of wholly-owned subsidiary DeKalb Genetics Corporation, the assignee of this application.

II. RELATED APPEALS AND INTERFERENCES

Appeals were filed in U.S. Patent Application Ser. No. 09/606,808; U.S. Patent Application Ser. No. 09/772,520; U.S. Patent Application Ser. No. 09/788,334; U.S. Patent Application Ser. No. 10/077,589; and U.S. Patent Application Ser. No. 10/077,591. The cases are not related to the current case but share the same Real Parties in Interest, are also directed to inbred corn plants, and present many of the same issues on appeal as this case and therefore may have a bearing on the Board's decision in the pending appeal.

III. STATUS OF THE CLAIMS

Claims 1-31 were filed with the application. Claims 4 and 26 were canceled in a Response to the Second Office mailed April 15, 2003. Claims 1-3, 5-25 and 27-31 were therefore pending at the time of the Third Office Action.

Claims 1, 5, 7-10, 12, 13 and 21 were indicated as allowed in the Third Office Action and claims 2, 3, 6, 11, 14-20 and 22-31 were rejected. No amendments have been made subsequent to the Third Office Action. The Examiner's Answer indicated that claims 1, 2, 5, 7-10, 12, 13 and 21-23 are now allowed. Therefore, claims 1-3, 5-25 and 27-31 are currently pending in the case. The rejections of pending claims 3, 6, 11, 14-20, 22-25 and 27-31 are the subject of this appeal. A copy of the appealed claims is attached as **Appendix 1** and a copy of the pending claims is attached as **Appendix 2**.

IV. STATUS OF AMENDMENTS

No amendments were made subsequent to the Third Office Action.

V. SUMMARY OF THE INVENTION

The invention relates to the novel inbred corn plant designated I015036 and seeds or populations of seed thereof. Specification at page 5, lines 5-22. The invention also relates to single locus converted plants of I015036. Specification at page 6, lines 12-21. The invention further relates to methods for breeding I015036 with other corn plants, and hybrid plants produced thereby. Specification from page 7, line 23 to page 9, line 16.

VI. ISSUES ON APPEAL

(1) Are claims 3, 6, 11, 14-18, 20 and 27-30 properly rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out the subject matter which applicants regard as the invention?

(2) Are claims 6, 11, 24, 25 and 27-31 properly rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to convey that the applicants were in possession of the claimed invention?

(3) Are claims 27-30 properly rejected under 35 U.S.C. §112, first paragraph, as lacking enablement?

VII. GROUPING OF THE CLAIMS

Claim 3 is directed to an essentially homogeneous population of seed of corn variety I015036, while claim 14 is directed to an essentially homogeneous population of corn plants produced by growing the seed of corn variety I015036. The analysis of issues on appeal for these claims turns on the meaning of "essentially homogeneous," and thus the claims stand or

fall together but separately from the remaining claims, which are directed to distinct subject matter with different issues on appeal. Claims 6 and 11 are directed to plants or plant parts having a specified marker profile. The appeal of the rejection of these claims turns on whether the marker profiles are described and enabled. None of the other claims present this issue and thus claims 6 and 11 stand or fall together but separately from the other claims. The appeal of the rejection of claims 15, 17 and 20 turns on the definiteness of the term "capable of expressing" and thus these claims present distinct issues on appeal. Claims 15, 17 and 20 therefore stand or fall together bus separately from the remaining claims. Claims 16-19 are directed to a corn plant capable of expressing all the physiological and morphological characteristics of the corn variety I015036 that further comprises a nuclear or cytoplasmic gene conferring male sterility. None of the other claims are directed to this subject matter and thus distinct issues are raised under 35 U.S.C. §112, first paragraph. Claims 16-19 therefore stand or fall together but separately from the remaining claims. Independent claims 22-23 are directed to a process of producing corn seed comprising crossing first and second corn plants, whereas claims 24-25 and 27-30 are directed to hybrid plants or seed produced by certain embodiments of this process. Process and product claims present different issues for the analysis of written description under 35 U.S.C. §112. Claims 22-23 thus stand or fall together but separately from the remaining claims. Claims 24-25 and 27-30 also stand or fall together but separately from the remaining claims. Another appealed independent process claim is present in the case in addition to claims 22-23, claim 31, but claim 31 comprises a distinct series of steps from these claims and thus presents different written description issues on appeal. Claim 31 therefore stands or falls alone.

VIII. SUMMARY OF THE ARGUMENT

The indefiniteness rejections fail because the metes and bounds of the claims are fully definite. The Examiner has failed to apply the proper standard under the second paragraph of §112. The indefiniteness rejections are each improper because the allegedly indefinite terms have a well known meaning such that one of skill in the art would understand the full metes and bounds of the claims.

The written description rejections fail because the claimed subject matter has been adequately described. Each of the claimed hybrid plants and seeds having inbred corn plant I015036 as one parent have as half of their genome the same genetic contribution from I015036, given that corn plant I015036 is inbred. This structural characteristic is readily detectable and thus defines the claimed plants. These plants can be produced using any second plant, thus written description with regard to the second parent is satisfied based on the countless corn varieties known to those of skill in the art. Methods of crossing the claimed corn variety have been fully described in the recited steps, and such corn breeding steps were well known in the art. Single locus conversions of I015036 were also fully described, in that well more than a representative collection of single locus conversion traits are described in the specification and were well known to those of skill in the art. The single locus conversion traits themselves are further not being claimed, rather it is corn plant I015036 comprising any given single locus conversion that is claimed.

The enablement rejections fail because Appellants working examples and descriptions in the specification fully enable the claimed subject matter. The Examiner has improperly disregarded this evidence and failed to support the rejections in contradiction of the standards of the APA.

IX. REPLY

The Examiner's Answer contains a substantial reiteration of the arguments previously presented and briefed. Appellants have responded only where further clarification is necessary in view of the Examiner's Answer.

A. The Indefiniteness Rejections Are Premised on a Misapplication of the Standard Under 35 U.S.C. §112, Second Paragraph

The Examiner has failed to apply the correct legal standard for an indefiniteness rejection. The Examiner's Answer throughout indicates that the claims have not been given a reasonable reading, in context, as one of skill in the art would view them when in possession of the specification. The Examiner appears to require absolute certainty of claim terms when read in isolation and by those unversed in the relevant art. This is not the correct standard. Viewed properly, the claim terms are fully definite.

The Federal Circuit has repeatedly made clear that absolute certainty in a claim is not required. The test for definiteness under 35 U.S.C. 112, second paragraph, is whether "those skilled in the art would understand what is claimed when the claim is read in light of the specification." *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986). The Examiner must consider the claim as a whole to determine whether the claim apprises one of ordinary skill in the art of its scope. *See, e.g., Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1379, 55 USPQ2d 1279, 1283 (Fed. Cir. 2000). This has not been done.

As explained in detail in the Appeal Brief, all of the claim terms have a well known meaning in the art when viewed in the context of the claims as a whole and with reference to the specification. Reversal of the rejections is thus respectfully requested.

B. The Written Description Rejections Are Improper

1. The Rejections Are Legally Incorrect

Despite statements in the Examiner's Answer to the contrary, the written description rejections were made based on the legally incorrect position that an applicant must show both a structure *and* a function for the structure in order to satisfy written description even when the structure describes the claimed invention. For example, after asserting that he "never placed a requirement that written description be satisfied in one specific manner," the Examiner states on page 22 that written description is not provided for the claimed hybrids because this "does not provide any information concerning the morphological and physiological characteristics that will be expressed by the claimed hybrids." The Examiner therefore required that hybrid plants be described by function (e.g., morphological traits), despite the fact that Appellants have provided direct ***structural support*** for the claimed plants at the genome level.

The correct legal standard does ***not*** require a structure and a function when the structure provided describes the claimed invention. Rather, an applicant must describe the claimed subject matter by "whatever characteristics sufficiently distinguish it." *Amgen v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206 (Fed. Cir. 1991). Here, what distinguishes the claimed plants is the shared genetic complement of parent plant I015036. Specifically, the claimed plants comprises as half of their genome one copy of the genome of corn plant I015036. The second haploid genome is from ***any different second corn plant***. This constitutes a description of concrete, distinguishable structural characteristics shared by all of the hybrid plants. This fully satisfies written description because what second parent contributes the other half of the genome is irrelevant to the production of a hybrid plant. The second plant cannot be said to be lacking description, because no particular plant is required and corn plants generally are known. It is black-letter law that written description must be viewed from the perspective of one of skill in

the art at the time the application is filed. *Wang Labs., Inc. v. Toshiba Corp.*, 993 F.2d 858, 863 (Fed. Cir. 1993). This has not been done by the Examiner.

The Answer attempts to downplay the structural description provided for what is claimed by arguing *ad absurdum* that "[a]ccording to Appellant's argument, any descendant, a 100th generation for example, of I015036 would be described, simply because some portion of the descendant's genome would have been present in the seed of corn variety I015036, and because seed of variety I015036 has been deposited." This is a misstatement. A 100th generation descendant is ***not*** what Appellants have claimed, which is all that is relevant to written description. Rather, a ***first*** generation progeny derived from inbred corn plant I015036 is claimed, which plant necessarily comprises as ***half*** of its genome a haploid copy of the genome of corn plant I015036 coupled with a haploid genome from ***any*** different second corn plant.

The complete structure of the claimed plants is therefore fully provided. First, the entire genetic complement of corn variety I015036 was described by biological deposit pursuant to the *Enzo* holding. Second, the identity of the second plant is irrelevant to whether a hybrid is produced. Third, thousands of corn plants that could serve as a second parent are well known to those of skill in the art, including several hundred having issued U.S. patents and biological deposits with the ATCC. Based on the seed deposits, those of skill in the art would immediately envision at least hundreds of hybrid plants down to the level of the DNA sequence of the plant genome. Given this detail of description the morphological traits are completely superfluous.

The fact that this description is made at the genetic level rather than by morphological traits in no way negatives written description. Written description is satisfied by describing structure characteristics allowing those of skill in the art to immediately "visualize or recognize the identity of the members of the genus. *The Regents of The University of California v. Eli Lilly*

and Co., 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Appellants have done precisely this by disclosing the genome of corn plant I015036 that is included in each of the claimed hybrid plants.

2. The rejection of claim 31 has not been adequately supported

The Examiner's Answer cites the "Revised Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. Sec. 112, ¶'Written Description' Requirement; Request for Comments, 64 Fed. Reg. 71427, 71428 (1999), comment no. 4 as support for the rejection of claim 31. This comment states the following:

> (4) Comment: Six comments were in favor of including process and product-by-process claims in the analysis, whereas one comment was opposed. One comment criticized the Guidelines for failing to acknowledge the "safe harbor" product-by-process type claim noted in Fiers v. Revel, 984 F.2d 1164, 25 USPQ2d 1601 (Fed. Cir. 1993), and Amgen Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991). One comment observed that process and product-by- process claims tend not to implicate many written description issues, and it may be useful to point out possible enablement deficiencies for such claims. Two comments suggested that the Guidelines should distinguish between claims to processes whose patentability depends on the compositions used in them, as opposed to those where patentability rests in the steps of the process itself. Response: The suggestion to address process and product-by-process claims has been adopted. Furthermore, the training materials will analyze claims wherein the patentability depends on the compositions used therein, as well as those where the patentability rests in the process steps themselves. Enablement issues raised by process and product-by-process claims are outside the scope of these Revised Interim Guidelines.

The comment was cited previously during prosecution as indicating that written description of a process claim requires a structural description of each intermediate product as if claimed in a product claim, *e.g.*, that process and composition claims are analyzed in the same way under the Guidelines. However, the Answer appears to state the opposite by acknowledging that the comment contemplates different treatment of product and process claims. Appellants respectfully submit that this contradicts the position taken by the Examiner. If product and process claims are treated differently there is no basis to allege that written description of a

process claims requires a description of products created in intermediate and penultimate steps as if claimed in a product claim. Therefore, as the only authority cited for the rejection supports Appellants position, it is respectfully submitted that the rejection is not supported by substantial evidence as required by the APA. *See In re Gartside*, 203 F.3d 1305, 1314-15 (Fed. Cir. 2000).

The Answer further acknowledges that the point of novelty must be taken into consideration when analyzing written description. While this may be true, the only composition upon which patentability rests and which is therefore relevant to the description of the claimed method is ***variety I015036.*** The Examiner does not contest that this variety has been fully described. What other products are used are irrelevant.

With regard to crossing corn plant I015036 with any second parent plant, the Examiner has acknowledged the description of this subject matter by the allowance of claims 21-22. Claim 22 in particular is directed to a process of producing F1 hybrid corn seed comprising crossing distinct inbred corn plants, one of which is a plant of the corn variety I015036. After crossing corn plant I015036 with a second parent plant, all of the remaining steps are routine breeding steps. The Examiner does not contest that corn breeding was routine in the art. Such plant breeding steps were also fully described in the specification. Given that the steps are routine breeding methods well known in the art and fully described in the specification, and the only composition upon which patentability depends has been acknowledged on the record to be described, it is submitted that description cannot reasonably be claimed to be lacking. *Wang Labs., Inc. v. Toshiba Corp.*, 993 F.2d 858, 863 (Fed. Cir. 1993) (Stating that written description must be reviewed from the perspective of one of skill in the art at the time the application is filed.).

In conclusion, all steps of the claimed process have been recited, all starting materials have been fully described, and methods of producing new corn varieties were well known to those of skill in the art. Claim 31 has therefore been fully described in compliance with 35 U.S.C. §112, first paragraph. Reversal of the rejection is thus respectfully requested.

C. Rejection of Claims Under 35 U.S.C. §112, First Paragraph - Enablement

The Examiner continues to assert the enablement rejection based on the contention that: (1) several references from species other than corn indicate difficulty in preparing single locus conversions, and (2) all single locus traits were not known and/or the corresponding phenotypic traits were not shown.

With regard to the first point, Appellants note that none of the references have been shown to have any relevance to *corn* plants. Hunsperger deals with petunias; Kraft with sugar beets and Eshed with Tomatoes. The relevance of the references to the claimed invention has therefore not been established as is specifically required to establish a *prima facie* case of non-enablement. Appellants pointed this out in the Appeal Brief, but the Answer simply disagrees without providing a scientific basis for doing so.

Appellants submit that the position taken is incorrect because corn breeding is extremely advanced and well known in the art as evidenced by the descriptions in the specification and references cited therein. This is due in large part to the fact that corn is one of the world's major food crops and largest seed crops. As explained in the specification, North American farmers alone plant ***tens of millions of acres*** of corn at the present time and there are ***extensive national and international commercial corn breeding*** programs. The market for corn seed in the U.S. alone is in excess of $2 billion (e.g., http://www.biotech-info.net/Distribution_benefits.pdf). No

basis has been shown to conclude that the same is true of the other plants and it is respectfully submitted that this is not true. The cited references therefore have not been shown to have any relevance to the claims.

The Examiner has not provided any basis other than opinion to suggest why the genetics of any of petunias, sugar beets or tomatoes are relevant to corn. Each of these plants are widely genetically diverged from maize – they are each classified as dicotyledonous plants whereas maize is a monocotyledonous plant. This distinction was noted by the Federal Circuit in *Plant Genetic Systems v. DeKalb Genetics Corp.*, in which a finding on non-enablement was affirmed because the claims read on both monocotyledonous and dicotyledonous plants, but were only enabled for dicotyledonous plants. 315 F.3d 1335 (Fed. Cir. 2003).

It therefore appears that the Examiner has improperly placed the burden to show enablement on Appellants. The indication that the references concerning petunias, sugar beets and tomatoes apply to corn is made without support. At the same time, the Examiner attempts to require Appellants to show why this is not true. While Appellants have nonetheless done so, it is respectfully noted that it is the ***Office*** that bears the burden of supporting its rejections. Appellants submit that this has not been done.

With regard to the particular genes used, Applicants have already shown over two pages well more than a representative number of genes for creation of single locus conversions. Further, the Examiner has provided no basis to indicate why the particular single locus used is relevant to production of the conversion. Using the well known procedures described in detail in the specification essentially any conversion can routinely be made. Appellants therefore submit that the current rejection is unsupported in fact or law. Reversal of the rejection is therefore respectfully requested.

X. CONCLUSION

It is respectfully submitted, in light of the above, none of the pending claims are properly rejected. Therefore, Appellants request that the Board reverse the pending grounds for rejection.

Respectfully submitted,

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Date: August 16, 2004

APPENDIX 1: CLAIMS ON APPEAL

3. The population of seed of claim 2, further defined as an essentially homogeneous population of seed.

6. The corn plant of claim 5, having:

(a) an SSR profile in accordance with the profile shown in Table 6; or

(b) an isozyme typing profile in accordance with the profile shown in Table 7.

11. The plant part of claim 10, wherein said cell is further defined as having :

(a) an SSR profile in accordance with the profile shown in Table 6; or

(b) an isozyme typing profile in accordance with the profile shown in Table 7.

14. An essentially homogeneous population of corn plants produced by growing the seed of the corn variety I015036, wherein a sample of the seed of the corn variety I015036 was deposited under ATCC Accession No. PTA-3225.

15. A corn plant capable of expressing all the physiological and morphological characteristics of the corn variety I015036, wherein a sample of the seed of the corn variety I015036 was deposited under ATCC Accession No. PTA-3225.

16. The corn plant of claim 15, further comprising a nuclear or cytoplasmically-inherited gene conferring male sterility.

17. A tissue culture of regenerable cells of a plant of corn variety I015036, wherein the tissue is capable of regenerating plants capable of expressing all the physiological and morphological characteristics of the corn variety I015036, wherein a sample of the seed of the corn variety I015036 was deposited under ATCC Accession No. PTA-3225.

18. The tissue culture of claim 17, wherein the regenerable cells comprise cells derived from embryos, immature embryos, meristematic cells, immature tassels, microspores, pollen, leaves, anthers, roots, root tips, silk, flowers, kernels, ears, cobs, husks, or stalks.

19. The tissue culture of claim 18, wherein the regenerable cells are in the form of protoplasts or callus cells.

20. A corn plant regenerated from the tissue culture of claim 17, wherein the corn plant is capable of expressing all of the physiological and morphological characteristics of the corn variety designated I015036, wherein a sample of the seed of the corn variety I015036 was deposited under ATCC Accession No. PTA-3225.

22. The process of claim 21, further defined as a process of producing F1 hybrid corn seed, comprising crossing a first inbred corn plant with a second, distinct inbred corn plant, wherein the first or second inbred corn plant is a plant of the corn variety I015036, wherein a sample of the seed of the corn variety I015036 was deposited under ATCC Accession No. PTA-3225.

23. The process of claim 22, wherein crossing comprises the steps of:

(a) planting the seeds of first and second inbred corn plants;

(b) cultivating the seeds of said first and second inbred corn plants into plants that bear flowers;

(c) preventing self pollination of at least one of the first or second inbred corn plant;

(d) allowing cross-pollination to occur between the first and second inbred corn plants; and

(e) harvesting seeds on at least one of the first or second inbred corn plants, said seeds resulting from said cross-pollination.

24. Hybrid corn seed produced by the process of claim 23.

25. A hybrid corn plant produced by growing a seed produced by the process of claim 23.

27. The corn plant of claim 5, further defined as having a genome comprising a single locus conversion. .

28. The corn plant of claim 27, wherein the single locus was stably inserted into a corn genome by transformation.

29. The corn plant of claim 27, wherein the locus is selected from the group consisting of a dominant allele and a recessive allele.

30. The corn plant of claim 27, wherein the locus confers a trait selected from the group consisting of herbicide tolerance; insect resistance; resistance to bacterial, fungal, nematode or viral disease; yield enhancement; waxy starch; improved nutritional quality; enhanced yield stability; male sterility and restoration of male fertility.

31. A method of producing an inbred corn plant derived from the corn variety I015036, the method comprising the steps of:

(a) preparing a progeny plant derived from corn variety I015036 by crossing a plant of the corn variety I015036 with a second corn plant, wherein a sample of the seed of the corn variety I015036 was deposited under ATCC Accession No. PTA-3225;

(b) crossing the progeny plant with itself or a second plant to produce a seed of a progeny plant of a subsequent generation;

(c) growing a progeny plant of a subsequent generation from said seed and crossing the progeny plant of a subsequent generation with itself or a second plant; and

(d) repeating steps (b) and (c) for an addition 3-10 generations to produce an inbred corn plant derived from the corn variety I015036.

APPENDIX 2: PENDING CLAIMS

1. A seed of the corn variety I015036, wherein a sample of the seed of the corn variety I015036 was deposited under ATCC Accession No. PTA-3225.

2. A population of seed of the corn variety I015036, wherein a sample of the seed of the corn variety I015036 was deposited under ATCC Accession No. PTA-3225.

3. The population of seed of claim 2, further defined as an essentially homogeneous population of seed.

5. A corn plant produced by growing a seed of the corn variety I015036, wherein a sample of the seed of the corn variety I015036 was deposited under ATCC Accession No. PTA-3225.

6. The corn plant of claim 5, having:
   (a) an SSR profile in accordance with the profile shown in Table 6; or
   (b) an isozyme typing profile in accordance with the profile shown in Table 7.

7. A plant part of the corn plant of claim 5.

8. The plant part of claim 7, further defined as pollen.

9. The plant part of claim 7, further defined as an ovule.

10. The plant part of claim 7, further defined as a cell.

11. The plant part of claim 10, wherein said cell is further defined as having:
    (a) an SSR profile in accordance with the profile shown in Table 6; or
    (b) an isozyme typing profile in accordance with the profile shown in Table 7.

12. A seed comprising the cell of claim 10.

13. A tissue culture comprising the cell of claim 10.

14. An essentially homogeneous population of corn plants produced by growing the seed of the corn variety I015036, wherein a sample of the seed of the corn variety I015036 was deposited under ATCC Accession No. PTA-3225.

15. A corn plant capable of expressing all the physiological and morphological characteristics of the corn variety I015036, wherein a sample of the seed of the corn variety I015036 was deposited under ATCC Accession No. PTA-3225.

16. The corn plant of claim 15, further comprising a nuclear or cytoplasmically-inherited gene conferring male sterility.

17. A tissue culture of regenerable cells of a plant of corn variety I015036, wherein the tissue is capable of regenerating plants capable of expressing all the physiological and morphological characteristics of the corn variety I015036, wherein a sample of the seed of the corn variety I015036 was deposited under ATCC Accession No. PTA-3225.

18. The tissue culture of claim 17, wherein the regenerable cells comprise cells derived from embryos, immature embryos, meristematic cells, immature tassels, microspores, pollen, leaves, anthers, roots, root tips, silk, flowers, kernels, ears, cobs, husks, or stalks.

19. The tissue culture of claim 18, wherein the regenerable cells are in the form of protoplasts or callus cells.

20. A corn plant regenerated from the tissue culture of claim 17, wherein the corn plant is capable of expressing all of the physiological and morphological characteristics of the corn variety designated I015036, wherein a sample of the seed of the corn variety I015036 was deposited under ATCC Accession No. PTA-3225.

21. A process of producing corn seed, comprising crossing a first parent corn plant with a second parent corn plant, wherein one or both of the first or the second parent corn plant is a plant of the corn variety I015036, wherein a sample of the seed of the corn variety I015036 was deposited under ATCC Accession No. PTA-3225, wherein seed is allowed to form.

22. The process of claim 21, further defined as a process of producing F1 hybrid corn seed, comprising crossing a first inbred corn plant with a second, distinct inbred corn plant, wherein the first or second inbred corn plant is a plant of the corn variety I015036, wherein a sample of the seed of the corn variety I015036 was deposited under ATCC Accession No. PTA-3225.

23. The process of claim 22, wherein crossing comprises the steps of:

(a) planting the seeds of first and second inbred corn plants;

(b) cultivating the seeds of said first and second inbred corn plants into plants that bear flowers;

(c) preventing self pollination of at least one of the first or second inbred corn plant;

(d) allowing cross-pollination to occur between the first and second inbred corn plants; and

(e) harvesting seeds on at least one of the first or second inbred corn plants, said seeds resulting from said cross-pollination.

24. Hybrid corn seed produced by the process of claim 23.

25. A hybrid corn plant produced by growing a seed produced by the process of claim 23.

27. The corn plant of claim 5, further defined as having a genome comprising a single locus conversion.

28. The corn plant of claim 27, wherein the single locus was stably inserted into a corn genome by transformation.

29. The corn plant of claim 27, wherein the locus is selected from the group consisting of a dominant allele and a recessive allele.

30. The corn plant of claim 27, wherein the locus confers a trait selected from the group consisting of herbicide tolerance; insect resistance; resistance to bacterial, fungal, nematode or viral disease; yield enhancement; waxy starch; improved nutritional quality; enhanced yield stability; male sterility and restoration of male fertility.

31. A method of producing an inbred corn plant derived from the corn variety I015036, the method comprising the steps of:

(a) preparing a progeny plant derived from corn variety I015036 by crossing a plant of the corn variety I015036 with a second corn plant, wherein a sample of the seed of the corn variety I015036 was deposited under ATCC Accession No. PTA-3225;

(b) crossing the progeny plant with itself or a second plant to produce a seed of a progeny plant of a subsequent generation;

(c) growing a progeny plant of a subsequent generation from said seed and crossing the progeny plant of a subsequent generation with itself or a second plant; and

(d) repeating steps (b) and (c) for an addition 3-10 generations to produce an inbred corn plant derived from the corn variety I015036.

AT

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/771,938	01/29/2001	Thomas B. Carlson	DEKA:281US/MBW	9121

7590 09/10/2004

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OIPE IAP64 JAN 26 2006 PATENT & TRADEMARK OFFICE

EXAMINER	
MEHTA, ASHWIN D	
ART UNIT	**PAPER NUMBER**
1638	

DATE MAILED: 09/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
09/771,938	1/29/2001	CARLSON	DEKA:281US

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EXAMINER	
MEHTA	
ART UNIT	**PAPER**
1638	9012004

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner for Patents

The reply brief filed 16 August 2004 has been entered and considered. The application has been forwarded to the Board of Patent Appeals and Interferences for decision on the appeal. Note: In the Reply Brief, under the section titled, "STATUS OF THE CLAIMS", Appellant correctly states that the Examiner's Answer indicated that claims 1, 2, 5, 7-10, 12, 13, and 21-23 are allowed. However, Appendix 1 of the Reply Brief, which is a list of appealed claims, erroneously includes claims 22 and 23, both of which are allowed.

The Examiner or Supervisory Patent Examiner requests the opportunity to present arguments at the oral hearing.

Any inquiry concerning this or earlier communications from the Examiner should be directed to Ashwin Mehta, whose telephone number is 571-272-0803. The Examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at 571-272-0804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

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September 1, 2004

Ashwin D. Mehta, Ph.D.
Primary Examiner
Art Unit 1638

PTO-90C (Rev.04-03)

Office Action Summary	Application No.	Applicant(s)
	09/532,687	LIVINGSTON, DAVID W.
	Examiner	Art Unit
	S. Mark Clardy	1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *Notice of Withdrawal from Issue, 7/28/05*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

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JAN 3 2006
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Disposition of Claims

4)☒ Claim(s) *12-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application (PTO-152)

6)☐ Other: _____.